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(71) Applicant *(for all designated States except US)*: **ADVANCED STENT TECHNOLOGIES, INC.** [US/US]; 6900 Koll Center Parkway, Suite 415, Pleasanton, CA 94566 (US).

(72) Inventors: **VARDI, Gil, M.**; 14203 Stifel Lane Court, Town and Country, MO 63017 (US). **DAVIDSON, Charles, J.**; 1131 Sunview Lane, Winnetka, IL 60093 (US). **WILLIAMS, Eric**; 2068 Davis Drive, Fairfield, CA 94533 (US). **YADIN, Amnon**; 5736 Owens Drive, Apt. 204, Pleasanton, CA 94588 (US). **MORIK, Yossi**; 100 East Huron, 1102-1103, Chicago, IL 60611 (US). **KONSTANTINO, Eitan**; 29 Meadow Park Court, Orinda, CA 94563 (US). **FELD, Tanhum**; Moshav Merhavia, 19105 ISRAEL (IL).

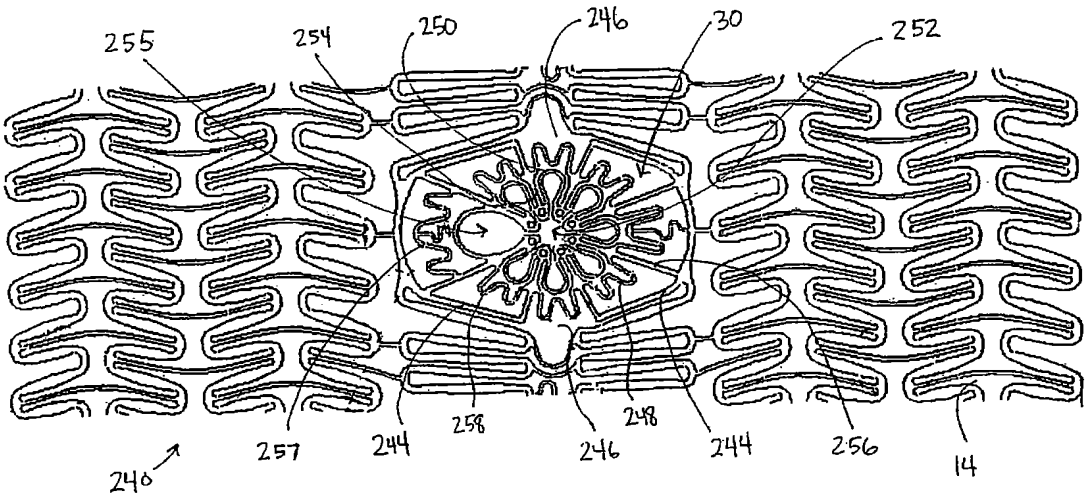
(74) Agent: **FRANK, Michele, Van Patten**; Patton Boggs LLP, 8484 Westpark Drive, 9th Floor, McLean, VA 22102 (US).

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[Continued on next page]

(54) Title: STENT WITH PROTRUDING BRANCH PORTION FOR BIFURCATED VESSELS



(57) Abstract: The present invention is directed to a stent (12) for use in a bifurcated body lumen having a main branch (2) and a side branch (4). The stent (12) comprises a radially expandable generally tubular stent body (14) having proximal (20) and distal (22) opposing ends with a body wall (14) having a surface extending therebetween. The surface has a geometrical configuration defining a first pattern, and the first pattern has first pattern struts (24) and connectors (26) arranged in a predetermined configuration. The stent (12) also comprises a branch portion (30) comprised of a second pattern, wherein the branch portion (30) is at least partially detachable from the stent body (14).

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STENT WITH PROTRUDING BRANCH PORTION FOR BIFURCATED VESSELS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of co-pending U.S. Patent Application No. 10/705,247, filed November 12, 2003, which claims the benefit of U.S. Patent Application No. 10/644,550, filed August 21, 2003, which claims the benefit of U.S. Provisional Application No. 60/404,756, filed August 21, 2002, U.S. Provisional Application No. 60/487,226, filed July 16, 2003, and U.S. Provisional Application No. 60/488,006, filed July 18, 2003, the entire contents of which are incorporated herein by reference.

[0002] The present application is also continuation-in-part of co-pending U.S. Patent Application No. 09/668,687, filed September 22, 2000, which is a continuation-in-part of U.S. Patent Application No. 09/326,445, filed June 4, 1999, which issued as U.S. Patent No. 6,325,826. The present application is also a continuation-in-part of U.S. Patent Application No. 10/440,401, filed May 19, 2003 which is a continuation of U.S. Patent Application No. 09/750,372, filed December 27, 2000, which issued as U.S. Patent No. 6,599,316. The present application is also a continuation-in-part of U.S. Patent Application No. 09/963,114, filed September 24, 2001, which is a continuation of U.S. Patent Application No. 09/326,445. U.S. Patent Application No. 09/326,445 is continuation-in-part of PCT Application No. US99/00835, filed January 13, 1999, which claims the benefit of U.S. Patent Application No. 09/007,265, filed January 14, 1998, which issued as U.S. Patent No. 6,210,429, which is a continuation-in-part of U.S. Patent Application No. 08/744,002, filed November 4, 1996. The entire contents of all of the above references are incorporated herein by reference.

FIELD OF THE INVENTION

[0003] The present invention relates to the field of medical stents and, more particularly, to a stent for the treatment of lesions and other problems in or near a vessel bifurcation.

BACKGROUND OF THE INVENTION

[0004] A stent is an endoprosthesis scaffold or other device that typically is intraluminally placed or implanted within a vein, artery, or other tubular body organ for treating an occlusion, stenosis, aneurysm, collapse, dissection, or weakened, diseased, or abnormally dilated vessel or vessel wall, by expanding the vessel or by reinforcing the vessel wall. In particular, stents are quite commonly implanted into the coronary, cardiac, pulmonary, neurovascular, peripheral vascular, renal, gastrointestinal and reproductive systems, and have been successfully implanted in the urinary tract, the bile duct, the esophagus, the tracheo-bronchial tree and the brain, to reinforce these body organs. Two important current widespread applications for stents are for improving angioplasty results by preventing elastic recoil and remodeling of the vessel wall and for treating dissections in blood vessel walls caused by balloon angioplasty of coronary arteries, as well as peripheral arteries, by pressing together the intimal flaps in the lumen at the site of the dissection. Conventional stents have been used for treating more complex vascular problems, such as lesions at or near bifurcation points in the vascular system, where a secondary artery branches out of a larger, main artery, with limited success rates.

[0005] Conventional stent technology is relatively well developed. Conventional stent designs typically feature a straight tubular, single type cellular structure, configuration, or pattern that is repetitive through translation along the longitudinal axis. In many stent designs, the repeating structure, configuration, or pattern has strut and connecting members that impede blood flow at bifurcations. Furthermore, the configuration of struts and connecting members may obstruct the use of post-operative devices to treat a branch vessel in the region of a vessel bifurcation. For example, deployment of a first stent in the main lumen may prevent a physician from inserting a branch stent through the ostium of a branch vessel of a vessel bifurcation in cases where treatment of the main vessel is suboptimal because of displaced diseased tissue (for example, due to plaque shifting or "snow plowing"), occlusion, vessel spasm, dissection with or without intimal flaps, thrombosis, embolism, and/or other vascular diseases. As a result, the physician may choose either to insert a stent into the branch in cases in which such additional treatment may otherwise be unnecessary, or alternatively the physician may elect not to treat, or to "sacrifice", such side lumen. Accordingly, the use of regular stents to treat diseased vessels at or

near a vessel bifurcation may create a risk of compromising the benefit of stent usage to the patient after the initial procedure and in future procedures on the main vessel, branch vessels, and/or the bifurcation point.

[0006] A regular stent is designed in view of conflicting considerations of coverage versus access. For example, to promote coverage, the cell structure size of the stent may be minimized for optimally supporting a vessel wall, thereby preventing or reducing tissue prolapse. To promote access, the cell size may be maximized for providing accessibility of blood flow and of a potentially future implanted branch stent to branch vessels, thereby preventing "stent jailing", and minimizing the amount of implanted material. Regular stent design has typically compromised one consideration for the other in an attempt to address both. Problems the present inventors observed involving side branch jailing, fear of plaque shifting, total occlusion, and difficulty of the procedure are continuing to drive the present inventors' into the development of novel, non-conventional or special stents, which are easier, safer, and more reliable to use for treating the above-indicated variety of vascular disorders.

[0007] Although conventional stents are routinely used in clinical procedures, clinical data shows that these stents are not capable of completely preventing in-stent restenosis (ISR) or restenosis caused by intimal hyperplasia. In-stent restenosis is the reoccurrence of the narrowing or blockage of an artery in the area covered by the stent following stent implantation. Patients treated with coronary stents can suffer from in-stent restenosis.

[0008] Many pharmacological attempts have been made to reduce the amount of restenosis caused by intimal hyperplasia. Many of these attempts have dealt with the systemic delivery of drugs via oral or intravascular introduction. However, success with the systemic approach has been limited.

[0009] Systemic delivery of drugs is inherently limited since it is difficult to achieve constant drug delivery to the inflicted region and since systemically administered drugs often cycle through concentration peaks and valleys, resulting in time periods of toxicity and ineffectiveness. Therefore, to be effective, anti-restenosis drugs should be delivered in a localized manner.

[0010] One approach for localized drug delivery utilizes stents as delivery vehicles. For example, stents seeded with transfected endothelial cells expressing bacterial beta-galactosidase or human tissue-type plasminogen activator were utilized as therapeutic protein delivery vehicles. *See, e.g.,* Dichek, D. A. *et al.,* "Seeding of Intravascular Stents With Genetically Engineered Endothelial Cells", *Circulation,* 80: 1347-1353 (1989).

[0011] U.S. Pat. No. 5,679,400, International Patent Application WO 91/12779, entitled "Intraluminal Drug Eluting Prosthesis," and International Patent Application WO 90/13332, entitled "Stent With Sustained Drug Delivery" disclose stent devices capable of delivering antiplatelet agents, anticoagulant agents, antimigratory agents, antimetabolic agents, and other anti-restenosis drugs.

[0012] U.S. Patents Nos. 6,273,913, 6,383,215, 6,258,121, 6,231,600, 5,837,008, 5,824,048, 5,679,400 and 5,609,629 teach stents coated with various pharmaceutical agents such as Rapamycin, 17-beta-estradiol, Taxol and Dexamethasone.

[0013] Although prior art references disclose numerous stents configurations coated with one or more distinct anti-restenosis agents, they do not disclose the inventive stent design of the present application. There is, therefore, a need for a stent design that can effectively provide ostial branch support in a vessel bifurcation and effectively act as a delivery vehicle for drugs useful in preventing restenosis. This is particularly true in complicated cases, such as lesions located at a bifurcation.

SUMMARY OF THE INVENTION

[0014] The present invention is directed to a stent for use in a bifurcated body lumen having a main branch and a side branch. The stent comprises a radially expandable generally tubular stent body having proximal and distal opposing ends with a body wall having a surface extending therebetween. The surface has a geometrical configuration defining a first pattern, and the first pattern has first pattern struts and connectors arranged in a predetermined configuration. The stent also comprises a branch portion comprised of a second pattern, wherein the branch portion is at least partially detachable from the stent body.

[0015] In one embodiment, the second pattern is configured according to the first pattern having at least one absent connector, and in another embodiment, the second pattern has a plurality of absent connectors. The second pattern may have second pattern struts, and the second pattern struts can be more densely packed than the first pattern struts.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented to provide what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the invention may be embodied in practice.

[0017] In the drawings:

[0018] FIG. 1 is an illustration of a blood vessel bifurcation having an obstruction;

[0019] FIGS. 2-4 are illustrations of prior art stents implemented at a blood vessel bifurcation;

[0020] Fig. 5 is a flat view of an embodiment of an unexpanded stent in accordance with the present invention;

[0021] FIG. 6 is an enlarged view of a portion of the unexpanded stent shown in FIG. 5;

[0022] FIG. 7 is a perspective view of the expandable branch portion of the stent of FIG. 5 in the expanded configuration;

[0023] FIG. 8 is an enlarged view of a portion of another embodiment of a stent according to the present invention;

[0024] FIG. 9 is an enlarged view of a portion of an alternative embodiment of a stent according to the present invention;

[0025] FIG. 10 is a perspective view of the expandable branch portion of the stent of FIG. 9 in the expanded configuration;

[0026] FIG. 11 is a schematic view of the stent of FIG. 5 in the expanded state implemented at a blood vessel bifurcation;

[0027] FIG. 12 is a schematic view of the stent of FIG. 9 in the expanded state implemented at a blood vessel bifurcation;

[0028] FIG. 13 is an enlarged view of a portion of another embodiment of a stent according to the present invention;

[0029] FIG. 14 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0030] FIG. 15 is an enlarged view of a portion of the unexpanded stent shown in FIG. 14;

[0031] FIG. 16 is a view of a portion of another embodiment of a stent according to the present invention;

[0032] FIG. 17 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0033] FIG. 18 is a perspective view of the expandable branch portion of the stent of FIG. 17 in the expanded configuration;

[0034] FIG. 19 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0035] FIG. 20 is an enlarged view of a portion of the stent of FIG. 19;

[0036] FIG. 21 is a view of the expandable branch portion of the stent of FIG. 19 in the expanded configuration;

[0037] FIG. 22 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0038] FIG. 23 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0039] FIG. 24 is a view of an expandable branch portion of the stent of FIG. 23 in the expanded condition;

[0040] FIGS. 25-28 are illustrations of the steps for a method of inserting a stent of the present invention, according to one embodiment.

[0041] FIGS. 29-31 are illustrations of the steps for another method of inserting a stent of the present invention.

[0042] FIG. 32 is a view of a herniated balloon for use with the method of FIGS. 29-31;

[0043] FIG. 33 is a view of another stent delivery system for inserting a stent in accordance with another method of the present invention;

[0044] FIG. 34 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0045] FIG. 35 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0046] FIG. 36 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0047] FIG. 37 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0048] FIG. 38 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0049] FIG. 39 is a perspective view of the stent of FIG. 38 in the expanded configuration;

[0050] FIG. 40 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0051] FIG. 41 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0052] FIG. 42 is a perspective view of the stent of FIG. 41 in the expanded configuration;

[0053] FIG. 43 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0054] FIG. 44 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0055] FIG. 45 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0056] FIG. 46 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention;

[0057] FIG. 47 is a perspective view of the stent of FIG. 46 in the expanded configuration; and

[0058] FIG. 48 is a flat view of another embodiment of an unexpanded stent in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0059] The present invention relates to stents for placement at vessel bifurcations and are generally configured to at least partially cover a portion of a branch vessel as well as a main vessel. Referring to FIG. 1, an exemplary blood vessel bifurcation **1** is shown, having a main vessel **2** extending along a main vessel axis **3** and a branch vessel **4** extending along a branch vessel axis **5**. Main vessel **2** and branch vessel **4** are disposed at an angle **11** of less than 90 degrees. An obstruction **6** is located within

bifurcation **1**, spanning or at least partially obstructing main vessel **2** and a proximal portion branch vessel **4**.

[0060] Prior attempts at relieving main vessel **2** and branch vessel **4** from obstruction **6**, such as the one depicted in FIG. 1, have been problematic. Referring to FIGS. 2-4, examples of prior methods and structures for stenting an obstructed bifurcation are shown. As shown in FIG. 2, a first stent **8** is introduced into main vessel **2** and an access hole or side opening in the wall of stent **8** is usually created with a balloon to provide access to branch vessel **4** and unobstructed blood flow thereto. Typically, the access hole is created by deforming the struts and connectors of the main stent pattern, which may also deform the area of the stent surrounding the created opening and lead to undesirable results. Also, if stent **8** is used alone, at least a portion of obstruction **6** located within branch vessel **4** is left without stent coverage. Referring to FIGS. 3 and 4, one prior solution has been to introduce a second stent **10** into branch vessel **4**, for example via a second catheter inserted through a side opening of first stent **8**. As can be seen in FIGS. 3 and 4, such a configuration may introduce additional problems. For example, as shown in FIG. 3, second stent **10** may not provide full coverage of the portion of obstruction **6** in branch vessel **4** due to the angle **11** of the side branch vessel **4** with respect to main vessel **2** and the fact that the ends of the stent typically define a right angle to the longitudinal axis of the lumen. Alternatively, second stent **10** may extend beyond the bifurcation into main vessel **2**, as shown in FIG. 4, and cause potential obstruction of blood flow in main vessel **2** and/or cause problems at the overlapping portions of stents **8** and **10**.

[0061] Referring now to FIGS. 5-7, a stent **12** according to one embodiment of the present invention comprises stent body or wall **14** extending along a longitudinal axis **16** from a proximal end **20** to a distal end **22** and defining a lumen **18** therein. Stent **12** may have a three-dimensional geometrical configuration having variable dimensions (length, width, height, depth, thickness, etc.). In a preferred embodiment, stent body **14** is a generally tubular structure. As defined herein, "tubular" can include an elongate structure that has varied cross-sections and does not require that the cross-section be circular. For example, the cross-section of stent wall **14** may be generally oval. In an alternate embodiment, stent body **14** is generally cylindrical. Also, the stent body **14** may have varied cross-sectional shapes along the longitudinal

axis **16** of the stent. For example, the circumferences in the proximal and distal parts of the stent may be different. This may occur, for example, if during stent delivery the delivery system causes the stent to distend. Lumen **18** represents the inner volumetric space bounded by stent body **14**. In a preferred embodiment, stent **12** is radially expandable from an unexpanded state to an expanded state to allow the stent to expand radially and support the main vessel. In the unexpanded state, stent body **14** defines a lumen **18** having a first volume, and in the expanded state, stent body **14** defines a lumen **18** having a second volume larger than the first volume.

[0062] FIG. 5 shows stent **12** in an unexpanded state in a flattened elevational view. As shown in FIG. 5, stent body **14** has a generally cellular configuration and comprises a generally repeatable series of struts **24** and connectors **26** configured in a predetermined general, overall, or main pattern along the length of stent **12**. Struts **24** comprise a pair of longitudinal strut portions **25** joined by a curved portion **27** at the proximal ends. Struts **24** are interconnected by curved portion **29** at the distal ends and formed into rings **28** that extend about the circumference of stent **12**. A series of the circumferential rings **28** are spaced apart from one another longitudinally along the entire length of stent **12**, and connectors **26** connect rings **28** to each other longitudinally. Connectors **26** extend generally longitudinally between adjacent circumferential rings **28** and connect to the respective curved portions **25**, **29** of longitudinally adjacent struts **24** of adjacent rings **28**. In a preferred embodiment, connectors **26** are generally S-shaped or zigzag-shaped, although other patterns may also be used. Details of patterns that may be used for stent **12** are described more fully in co-pending PCT application IL02/00840, filed October 20, 2002, incorporated herein by reference in its entirety. Furthermore, many other strut and connector patterns may be used, and the present pattern is shown for illustration purposes only.

[0063] Stent **12** further includes a branch portion **30** located at some point along the length of stent **12**. Branch portion **30** comprises a section or portion of stent wall **14** that is configured to extend into a branch vessel in a vessel bifurcation. In general, branch portion **30** is configured to be movable from an unextended position to an extended position. In the unextended position, branch portion **30** is disposed in the volume defined by the unexpanded stent **12**, that is, the branch portion **30** does not protrude radially from stent wall **14**. In the extended position, the branch portion **30**

extends outwardly from stent wall **14** and branch portion **30** is extended into the branch vessel. As best seen in FIG. 6, branch portion **30** comprises a stent wall section of stent body **14** that is initially flush, coplanar, or cocylindrical with the remainder of stent body **14** and may extend outwardly with respect to the remainder of stent body **14**. In this regard, branch portion **30** is generally adjacent an opening, slit, space, void, or other incongruity in the overall or main pattern of stent body **14**. This configuration allows for access into a branch vessel, and at the same time allows for circumferential alignment of the stent within the vessel prior to deployment. In other embodiments, multiple branch portions can be incorporated into the stent to permit multiple access to one or more vessels. In a preferred embodiment, branch portion **30** may be positioned in the midsection of stent **12**. In alternate embodiments, branch portion **30** may be positioned anywhere along the length of stent **12**.

[0064] As best seen in FIG. 6, in a first embodiment, branch portion **30** comprises a portion of branch ring **32** and is positioned adjacent and proximal to an opening **34**. Upon extension of branch portion **30**, the portion of branch ring **32** adjacent opening **34** extends into the branch vessel, whereas the circumferential ring **28** adjacent branch ring **32** does not extend into the branch vessel. Opening **34** is formed by an absence of at least one connector **26** adjoining branch ring **32** with a branch opposing ring **33**. In some embodiments, four adjacent connectors are absent; however, in alternate embodiments any number of connectors may be absent to create opening **34**. In this embodiment, branch ring **32** is substantially similar geometrically to circumferential rings **28** and comprises branch ring struts **36** substantially similar to struts **24**; however, a plurality of adjacent struts are free from connectors **26** adjacent opening **34**. In this regard, branch ring **32** is at least partially detachable from stent body **14** to facilitate at least a portion of branch ring **32** to extend outwardly with respect to stent body **14**. In some embodiments, the geometry of branch ring **32** may vary with respect to circumferential rings **28**, and branch ring struts **36** may have different configurations than struts **24**.

[0065] When stent **12** is expanded, as shown in FIG.7, branch portion **30** is extended into the branch vessel, causing a portion of branch ring **32** to at least partially cover the inner surface of the branch vessel **4**. Thus, in a preferred embodiment, the stent

coverage in the branch vessel includes at least partial coverage of the proximal side of the inner branch vessel wall.

[0066] Various alternative embodiments provide varying geometries of branch portion **30**. For example, branch ring **32** may vary with respect to circumferential rings **28**, and branch ring struts **36** may have different configurations than struts **24**. In one alternate embodiment, branch ring struts **36** are longer than struts **24**. In another embodiment, branch ring struts **36** are more closely packed circumferentially, resulting in a greater number of branch ring struts **36** per area within branch ring **32** as compared to circumferential rings **28**. In another embodiment, branch ring struts **36** may be thinner than struts **24**. In yet another embodiment, branch ring struts **36** may be made of a different material than struts **24**.

[0067] Referring to FIG. 8, another alternate embodiment of stent **19** is shown wherein a branch portion **30** comprises a branch ring **32** having branch ring struts **36** that are longer than struts **24** and a greater number of branch ring struts **36** provided as compared to the number of struts 24 in circumferential rings **28**, resulting in a more closely packed branch ring **32**. Furthermore, the number of branch ring connectors **38** on both sides of branch ring **32** is lower per branch strut **36** than the number of connectors **26** per strut **24**. Opening **34** is adjacent branch ring **32** on a distal side thereof, and the distal ends **46** of at least one, and preferably a plurality, of branch ring struts **40, 42, 44** are free from connectors and detachable from stent body **14**. In this embodiment, two branch ring struts **48** and **50** positioned laterally adjacent struts **40, 42,** and **44** have proximal ends **52** free from connectors. In this regard, free proximal ends **52** provide less resistance to movement of branch ring **32** during outward expansion with respect to stent body **14**. This same procedure can be used to provide one, two, three or more proximal ends in the ring free of connectors. Additionally, the shape and configuration of branch ring connectors **38** is different than those of connectors **26**. For example branch ring connectors along the proximal side of branch ring **32** are longer than connectors **26** to facilitate greater expansion of branch portion **30** into a vessel side branch. Also, branch ring connectors along the distal side of branch ring **32** are shaped and oriented differently than connectors **26** to facilitate greater expansion of branch portion **30** into the branch vessel. In alternate embodiments, branch ring connectors **38** may also differ among themselves. Also,

the longer branch ring struts **36** are generally more flexible than comparable shorter struts because the added length permits more deflection. Also, the added length permits greater coverage vessel wall coverage due to deeper penetration into the branch vessel during extension. In alternate embodiments, different geometries and orientations of branch ring connectors **38** may be used.

[0068] Referring to FIG. 9, another alternate embodiment of stent **29** is shown having a branch portion **30** similar to that of the embodiment of FIG. 8, except branch ring struts **40, 42,** and **44** are longer than the other branch ring struts **36,** and the distal ends thereof define an arcuate profile to the proximal side of opening **34**. Also, central strut **42** is longer than struts **40, 44** adjacent to strut **42**. In this regard, when branch portion **30** is extended, struts **40, 42,** and **44** extend further into the branch vessel and provide more coverage of the vessel wall than the embodiment depicted in FIG. 8. In this regard, this embodiment may more readily cover an obstruction in a bifurcation vessel such as the one depicted in FIG. 1 and, therefore, may provide better blood flow to a branch vessel. Furthermore, as described in more detail below, this embodiment facilitates the use of a second stent in the branch vessel.

[0069] Referring to FIG. 10, stent **29** of FIG. 9 is shown in an expanded state with branch portion **30** extended into the branch vessel, causing branch ring **32** to at least partially cover the inner surface of the branch vessel on the proximal side. The distal end of strut **42** of branch ring **32** extends further into the branch vessel than the distal ends of struts **40, 44** because strut **42** is longer in this embodiment than adjacent struts **40, 44**. In this regard, a generally tapered, straight or linear profile along the distal perimeter of branch portion **30** is created when branch portion **30** is expanded into the branch vessel.

[0070] Referring to FIGS. 11 and 12, schematic views are shown of stents **12, 29** of FIGS. 5 and 9, respectively, in the expanded state as implemented at a blood vessel bifurcation. As shown in FIG. 11, stent **19** of the embodiment of FIG. 8 has a generally curved or radial profile along the distal perimeter **45** of branch portion **30** as it extends into branch vessel **4**. The generally curved or radial profile is due to the particular geometry of branch portion **30** of stent **19** of the embodiment of FIG. 8. In particular, because all of the branch ring struts **36** of branch ring **32** are of equal length in this embodiment, the distal ends of struts **36** radially expand equidistantly

into branch vessel **4**, thereby creating a generally curved or radial profile along the distal perimeter **45** of branch portion **30**. Referring to FIG. 12, stent **29** of the embodiment of FIG. 9 has a generally tapered, straight or linear profile along the distal perimeter **47** of the branch portion **30** of the stent as it extends into branch vessel **4**. The generally straight or linear profile in FIG. 12 is a result of the particular geometry of branch portion **30** of stent **29** of the embodiment of FIG. 9. In particular, because central strut **42** of branch ring **32** is longer in this embodiment than struts **40, 44** adjacent to strut **42**, the distal end of strut **42** extends further into branch vessel **4** than the distal ends of struts **40, 44**, as best seen in FIG. 10, thus creating a generally tapered, straight or linear profile along the distal perimeter of branch portion **30**. In a preferred embodiment, the linear profile is at a right angle with respect to the axis of branch vessel **4**. In alternative embodiments, however, the linear profile may be at any angle with respect to the axis of branch vessel **4**. One advantageous feature of the linear profile along the distal perimeter of branch portion **30** shown in FIG. 12 is that if a second stent **51** were to be used in branch vessel **4**, the linear profile facilitates better alignment with the second stent and permits coverage of a larger surface area of the branch vessel wall. For example, if a second stent **51** were to be used in combination with stent **12** of FIG. 11, gaps may exist between the two stents at the interface between the radial distal perimeter **45** and an abutting straight or linear edge of a second stent, whereas a close abutting interface may be achieved with stent **29** of FIG. 12.

[0071] Referring to FIG.13, another embodiment of stent **39** is shown having an alternative embodiment of a branch portion **30** similar to that of the embodiment of FIG. 9, except lateral branch ring struts **48** and **50** are longer than the other branch ring struts **36**, and the proximal ends **52** of branch ring struts **48, 50** extend proximally beyond the other branch ring struts into a space between the branch ring **32** and the adjacent circumferential ring **28**. Branch ring struts **48, 50** have proximal ends **52** free from connectors and provide less resistance to movement of branch ring **32** during outward expansion with respect to stent body **14**. In this regard, the longer lateral branch ring struts **48, 50** function similar to a hinge and further facilitate extension of branch ring portion **30** outwardly, which may accommodate a branch vessel disposed at a greater angle **11** (Fig. 1) as compared to stent **29** of the embodiment of FIG. 9. Again, since struts **40, 42**, and **44** are longer than branch ring struts **36**, they are more

flexible and provide more coverage of a vessel wall than the embodiment depicted in FIG. 8.

[0072] Referring now to FIGS. 14 and 15, another embodiment of stent **49** is shown having a stent body **14** that has a longitudinal section **53** that has a different pattern than main pattern **54**. Longitudinal section **53** comprises a generally repeatable series of struts **56** and connectors **58** that are smaller in dimension than struts **24** and connectors **26**, but are formed into a similar geometrical pattern as main pattern **54**. In this regard, the struts **56** are more numerous per area within rings **28**, and rings **28** are more numerous per area in section **53** because the length of struts **56** is shorter than the length of struts **24** and the length of connectors **58** is shorter than the length of connectors **26**. In a preferred embodiment, the same number of connectors **58** extend between adjacent rings **28**; however, because the struts are more numerous in longitudinal section **53**, connectors **58** extend longitudinally between every other strut of adjacent rings **28**. As shown in FIG. 15, stent **49** further includes a branch portion **30** positioned within section **53**. Branch portion **30** comprises a branch ring **32** adjacent an opening **34**. Opening **34** is formed by an absence of at least one connector **26** adjoining branch ring **32** with branch opposing ring **33**. In a preferred embodiment, two adjacent connectors are absent; however, in alternate embodiments any number of connectors may be absent to create opening **34**. In this embodiment, branch ring **32** is substantially similar geometrically to circumferential rings **28** and comprises branch ring struts **36** substantially similar to struts **56**; however, a plurality of adjacent struts are free from a connectors **58** adjacent opening **34** and branch ring **32** is at least partially detachable from stent body **14** at opening **34** to facilitate at least a portion of branch ring **32** to extend outwardly with respect to stent body **14**. The generally smaller struts and connectors of longitudinal section **53** provide for freer movement of the strut and connector material and facilitate conformance to a vessel wall. The smaller struts and connectors also provide for a relatively more dense surface area coverage of the branch vessel wall, which may be advantageous in achieving a more uniform coverage around the ostium. In particular, this embodiment may provide particularly advantageous coverage of a geometrically complex obstruction in a bifurcation vessel since the relatively small pattern may flex or contour around the obstruction and provide coverage therefor. Also, this embodiment

is advantageous for relatively small obstructions as the smaller pattern may cover more surface area of obstruction.

[0073] Referring to FIG. 16, another embodiment of stent **59** is shown and includes an alternate branch portion **30** comprising a portion of three adjacent branch ring sections **60, 62, 64** connected and extending circumferentially from two adjacent circumferential rings **28**. Branch ring sections **60, 62, 64** each includes a plurality of branch struts **66** and are connected in the longitudinal direction by branch connectors **68**. Struts **66** are shorter longitudinally than struts **24** of rings **28** and connectors **68** are smaller than connectors **26**. The distal ring **60** is adjacent opening **34** and the distal ends of struts **66** of ring **60** are detachable from stent body **14** at opening **34** to permit extension of at least a portion of branch ring sections **60, 62, 64** to expand outwardly with respect to stent body **14**. In this embodiment, the three branch ring sections **60, 62, 64** may extend outwardly in a more radial fashion and this branch portion **30** may be particularly advantageous for adapting or conforming to the shape of the proximal side of the ostium. Furthermore, the branch portion of this embodiment may more readily extend or flex around an obstruction in a bifurcation vessel such as the one depicted in FIG. 1 while providing branch wall coverage and better blood flow to the branch vessel.

[0074] Referring to FIGS. 17 and 18, an alternate embodiment of stent **69** is shown and includes an alternate branch portion **30**. In this particular embodiment, branch portion **30** comprises support struts **70** and an expandable ring **72**. Branch portion **30** defines at least one side opening **74**. In one embodiment, the dimensions of the cell defining side opening **74** are such that the side opening 74 (prior to expansion of the stent) is larger than other openings in stent body 14. The presence of side opening 74 is generally configured to accommodate a side sheath therethrough and allow a physician to access a branch vessel during or after a procedure. In a particular embodiment, as shown in FIG. 17, side opening **74** is surrounded by expandable ring **72** of continuous material. In alternative embodiments, expandable ring **72** comprises unattached portions, or one portion that only partially covers side opening **74**. A series of support struts **70** connect expandable ring **72** with struts **24** and connectors **26**. Support struts **70** preferably comprise patterns in a folded or wrap-around

configuration that at least partially straighten out during expansion, allowing expandable ring **72** to protrude into the branch vessel.

[0075] In this embodiment, when stent **69** is expanded, as shown in FIG. 18, branch portion **30** is extended into the branch vessel, causing expandable ring **74** to at least partially cover the inner surface of the branch vessel. Thus, in a preferred embodiment, the stent coverage in a portion the branch vessel includes the full circumference of the inner branch vessel wall. In alternative embodiments, partial coverage or several sections of coverage are present.

[0076] Referring to FIGS. 19-21, another embodiment of a stent **79** is shown having a main stent body **14** and another embodiment of a branch portion **30**. FIGS. 19 and 20 show stent **79** in the unexpanded condition where branch portion **30** has not been deployed. FIG. 21 shows the stent **79** in the expanded configuration where the branch portion **30** has been expanded. As shown, main stent body **14** includes a main stent pattern having a generally repeatable ring **28** and connector **26** pattern. Branch portion **30** and the surrounding midsection **80** interrupt the repeatable ring **28** and connector **26** pattern of stent **79**. In this embodiment, branch portion **30** is configured to be both radially expandable and longitudinally extendable into the branch vessel and relative to its longitudinal axis **83** so that, in a preferred embodiment, the branch portion **30** contacts the entire periphery or circumference of the inner wall of the branch vessel in the expanded configuration. In this regard, branch portion **30** preferably provides 360° coverage of the wall of the branch vessel. That is, branch portion **30** can be extended outward with respect to longitudinal axis **81** of stent **79**, and can also be expanded radially about axis **83** so as to contact the vessel (thereby allowing it to be adjustable with respect to vessel size).

[0077] Referring to FIG. 20, an enlarged view of section **80** of stent **79** is shown. In a preferred embodiment, a structural support member **84** may be provided as a transition between the main stent body **14** and branch portion **30**. In one aspect of a preferred embodiment, structural support member **84** may be elliptical to accommodate branch vessels extending at an angle to the main vessel. In alternate embodiment, other shapes of support member **84** can be used to accommodate the vasculature. The structural support member **84** may include a continuous ring. In this

embodiment, structural support member **84** is a full, non-expandable ring and it does not expand radially beyond a particular circumference.

[0078] As shown in FIGS. 19 and 20, two concentric rings, inner ring **86** and outer ring **88**, are positioned within structural support member **84** and surround a generally circular central branch opening **34** to provide access to the side branch vessel when stent **79** is in the unexpanded condition. Rings **86** and **88** are interconnected by a plurality of inner connectors **90**. Outer ring **88** is connected to structural support member **84** by a plurality of outer connectors **92**. Rings **86** and **88** are generally curvilinear members. For example, rings **86, 88** can be defined by undulation petals, prongs, or peaks **94**. In a preferred embodiment, each ring **86, 88** have the same number of undulation peaks **94**, but the inner ring may be more closely or tightly arranged, as shown. In another preferred embodiment, each ring **86, 88** has eight pedals or undulation peaks **94**, although in alternate embodiments each ring can have any number of undulation peaks, and the number of peaks need not be equal for each ring. The undulation peaks **94** generally include a pair of strut portions **96** interconnected by curved portions **98**, and the strut portions themselves are connected to adjacent strut portions by another curved portion. In a preferred embodiment, eight outer connectors **92** extend between structural support member **84** and outer ring **88**, and each outer connector **92** is attached at one end to approximately the middle of a strut portion **96** of outer ring **88** and the structural support member **84** at the other end. As shown, outer connectors **92** may also have an undulated shape, although in alternate embodiments outer connectors **92** may have differing shapes. In another aspect of the preferred embodiment, outer connectors **92** may be evenly or symmetrically spaced about the structural support member **84**. The inner ring **86** is attached to the outer ring **88** by a plurality of inner connectors **90** and, in a preferred embodiment, eight inner connectors **90** connect the rings. Inner connectors **90** extend from curved portion **98** of outer ring **88** to curved portion of inner ring **86**. As shown in FIG. 20, in a preferred embodiment, inner connectors **90** have a simple curved shape. Other quantities, configurations, sizes and arrangements of connectors, rings and spacing can be used depending upon the desired results. Varying the connectors can provide for different amounts of flexibility and coverage. The type of configuration of rings and connectors shown addresses the need for radial and longitudinal expansion of branch portion **30**, as well as branch vessel coverage.

Other configurations and arrangements for the branch portion can be used in accordance with the invention.

[0079] Referring again to FIGS. 19 and 20, the stent pattern surrounding branch portion **30** may be modified with a different pattern to accommodate branch portion **30**, as can all of the aforementioned embodiments. In particular, the rings **28** in the midsection **80** may be configured and dimensioned to be denser to provide sufficient coverage and flexibility to compensate for the area occupied by branch portion **30**.

[0080] Referring now to FIG. 21, stent **79** is shown in the expanded configuration, with branch portion **30** deployed. Upon expansion of branch portion **30**, the inner and outer rings **86, 88** shift about the longitudinal branch axis **83** and expand laterally away from the main stent body **14** and into the branch vessel to form a branch coverage portion. Upon expansion, the outer connectors **92** can move outwardly and the inner connectors **90** can straighten to a position substantially parallel to longitudinal branch axis **83**. In a preferred embodiment, the expanded rings **86, 88** have substantially the same expanded diameter, although in alternate embodiments rings **86, 88** could also have different diameters to accommodate a tapered vessel, if, for example a tapered balloon is used. The branch portion **30** can be extended at different angles to the longitudinal axis **81** of the stent depending upon the geometry of the branch vessel being treated. In this embodiment, the branch portion **30** may preferably extend into the branch vessel about 1.5 – 3 mm.

[0081] Referring now to FIG. 22, another embodiment of a stent **89** is shown having a main stent body **14** and another embodiment of a branch portion **30**. Stent **89** is substantially similar to stent **79**, except stent **89** has a discontinuous support member **104** surrounding a two concentric ring **86, 88** structure. Support member **104** has a generally elliptical shape and includes a plurality of discontinuities **106** along the perimeter. The configuration of the discontinuous support member facilitates additional flexibility of the branch portion during expansion and generally provides for accommodating a greater range of branch vessel geometries. In one aspect of a preferred embodiment, structural support member **84** may be elliptical to accommodate branch vessels extending at an angle to the main vessel.

[0082] Referring to FIGS. 23 and 24, another embodiment of a stent **99** is shown in the unexpanded and expanded states, respectively. Stent **99** comprises a main stent body **14** and another embodiment of a branch portion **30**. Stent **99** is substantially similar to stent **79**, except stent **99** has a branch portion **30** including a support member **108** surrounding three concentric rings **110, 112, 114** instead of two. As can be seen in FIG. 24, when stent **99** is expanded the three concentric ring structure of this embodiment facilitates additional branch wall support because a generally more dense pattern is created in branch portion **30** with the addition of another concentric ring.

[0083] Referring to FIG. 34, an alternate embodiment of a stent **220** is shown having a main stent body **14** and another embodiment of branch portion **30**. FIG. 34 is a flat view of stent **220** shown in an unexpanded condition where branch **30** has not been deployed. Main stent body **14** includes a main stent pattern having a generally repeatable ring **28** and connector **26** pattern. Branch portion **30** and the surrounding midsection **80** interrupt the repeatable ring **28** and connector pattern of stent **220**. Branch portion **30** is configured to be extendable into the branch vessel such that the branch portion **30** contacts the entire periphery or circumference of the inner wall of the branch vessel in the expanded configuration.

[0084] In a preferred embodiment, transition members **224** may be provided as a transition between the main stent body **14** and branch portion **30**. Transition members **224** comprise generally elliptical half portions positioned in an opposing relation with a space **246** therebetween. Transition members **224** surround a two concentric ring **228, 230** structure and a central branch opening **232**. Branch opening **232** provides access to the side branch vessel when stent **220** is in the unexpanded condition and a side sheath may pass through opening **232**. Rings **228** and **230** are interconnected by a plurality of inner connectors **234**. Outer ring **230** is connected to transition members **224** by a plurality of outer connectors **236**. Rings **228, 230** are generally curvilinear members and include undulation petals, prongs, or peaks **238**. In this embodiment outer ring **230** includes a greater number of peaks than inner ring **228**. Preferably eight outer connectors and eight inner connectors interconnect transition members **224** and rings **228, 230**. In this embodiment, inner and outer connectors **234, 236** are generally straight members and are preferably aligned radially to extend

toward the center of branch portion **30**. In operation, the intersection of outer connectors **236** with transition members **224** form a pivot point about which petals **238** may unfold or pivot outward into the side branch vessel. In a preferred embodiment, the generally straight inner and outer connectors pivot together such that the petals **238** open like a flower.

[0085] Referring to FIG. 35, an alternative embodiment of a stent **240** is shown having an alternate embodiment of a branch portion **30**. Stent **240** includes structural support members **244** as a transition between the main stent body **14** and branch portion **30**. Support members **244** comprise generally elliptical half portions positioned in an opposing relation with a space **246** therebetween. Support members **244** surround a two concentric ring **248, 250** structure and a central branch opening **252**. Rings **248** and **250** are interconnected by a plurality of inner connectors **254**. Outer ring **248** is connected to structural support members **244** by a plurality of outer connectors **256**. Rings **248, 250** are generally curvilinear members and include undulation petals, prongs, or peaks **258**. An auxiliary access opening **255** interrupts rings **248, 250** and provides access to the side branch vessel when stent **240** is in the unexpanded condition. A ring portion **257** extends between outer connectors **256** proximal to auxiliary access opening **255**. In this embodiment, auxiliary access opening **255** is generally larger than central branch opening **252** to more readily receive a side sheath therethrough and to allow for greater access to the side branch. Auxiliary access opening **255** is preferably positioned proximal to central branch opening **252** when loaded on a stent delivery system, however auxiliary access opening **255** can have varying positions in alternate embodiments An alternate embodiment of a stent **260** is shown in FIG. 36 that is similar to stent **240** and it additionally includes lateral connecting members **262** that extend through space **246** and connect the outer ring **250** to struts **264** laterally outside branch portion **30**. In this regard, when branch portion **30** is extended into the side branch, struts **264** are pulled radially inward to support the circumference of the ostium. This additional structure improves radial strength and provides additional support to the vessel wall.

[0086] Referring to FIG. 37, an alternate embodiment of a stent **280** is shown that is similar to stent **260** and includes lateral connecting members **282** that extend through space **246** and connect the outer ring **250** to struts **284** laterally outside branch

portion **30**. Struts **284** are generally longitudinal connecting members spanning longitudinally between adjacent strut rings **286, 288**. In this embodiment, struts **284** are generally curved members having a general omega shape. Struts **284** have a smaller radius of curvature than struts **264** of stent **240** described above. When branch portion **30** is extended into the side branch, struts **284** are pulled radially inward to support the circumference of the ostium. In addition, the general omega shape and comparatively smaller radius of curvature allow for greater expansion of struts **284** and permits greater movement or expansion of branch portion **30** without affecting deformation of the surrounding midsection **80**. In alternate embodiments, other geometries of struts **284** may be used to accomplish the same purpose.

[0087] Referring to FIGS. 38 and 39, an alternate embodiment of a stent **290** is shown that is similar to stent **280**, described above, and generally includes at least one omega shaped connecting member **292** extending longitudinally outside branch portion **30** and connecting the midsection **80** to the repeatable ring **28** and connector **26** pattern of main stent body **14**. As with prior embodiments, branch portion **30** is configured to be extendable into the branch vessel such that the branch portion **30** contacts the entire periphery or circumference of the inner wall of the branch vessel in the expanded configuration. Also, because midsection **80** has a different pattern than the main stent body, midsection **80** may expand radially to a different extent than the main stent pattern when branch portion **30** is extended into the side branch vessel. Connecting members **292** are configured to expand or contract accordingly to accommodate differential expansion of midsection **80** with respect to the main stent body. In this regard, connecting members **292** provide a cushion, dampening member, or act as a buffer between the expansion of the main stent body **14** and midsection **80** so that the expansion of main stent body **14** has a limited effect on the midsection **80** in operation and vice versa. In particular, the generally omega shape of connecting members **292** allow for greater expansion of connecting members **292** as compared to straight or substantially straight connector geometries. In alternate embodiments, other geometries of connecting members **292** may be used to accomplish the same purpose, that is to provide a cushion, dampen, or buffer the expansion of the midsection **80** with respect to the main stent body **14**.

[0088] Referring to FIG. 40, an alternate embodiment of a stent **300** is shown that is similar to stent **290**, described above, and generally includes a branch portion **30** including an outer ring **302**, and an inner ring **304**. The inner ring defines undulation petals, prongs, or peaks **306** surrounding a central branch opening **308**. Branch opening **308** provides access to the side branch vessel when stent **300** is in the unexpanded condition. In this embodiment, undulation peaks **306** of inner ring **304** have a relatively larger radius of curvature, *i.e.* they are less pointed, than, for example, the corresponding peaks **238** of inner ring **228** of stent **220**, described above. For example, in a preferred embodiment peaks **306** may have a radius of curvature in the range of about 0.125 mm to about 0.225 mm, and preferably about 0.170 mm. In comparison, in a preferred embodiment peaks **238** of stent **220** may generally have a radius of curvature between about 0.025 mm to about 0.125 mm. In this regard, the geometry of peaks **306** may permit and/or facilitate the use of particular balloon types and designs. In particular, the design and shape of peaks **306** in this embodiment are less likely to pinch or puncture certain balloon designs. Although, in this embodiment branch portion **30** does not include an auxiliary access opening **255** to provide access to the side branch vessel, as with stents **240, 260, 280,** and **290,** in alternative embodiments, branch portion **30** may include such an auxiliary access opening. Referring to FIGS. 41 and 42, an alternative embodiment of a stent **320** is shown that is similar to stent **300**, described above, except the inner ring **324** has undulation peaks **326** with a smaller radius of curvature than peaks **308** described above. Also, in this embodiment each peak **326** defines a hole configured and dimensioned to accommodate, for example, a marker.

[0089] Referring to FIGS. 43-45, alternate embodiments of stents are shown having a main stent body **14** with alternative main stent pattern designs. In the embodiments of FIGS. 43-45, the main stent patterns have an open cell structure. For example, stents **340, 350, 360,** each have a main stent body **14** having a generally repeatable ring **28** and connector **26** pattern and the connectors **26** are spaced apart and alternate every two or three strut pairs defining a more open cell structure as compared to providing connectors spaced apart or alternating every strut pair. In this regard, stents **340, 350, 360,** have less stent material making up the main stent body and can have desirable clinical effects in certain applications. For example, if the stent is made from a metal material, it can be beneficial to have a smaller metal surface area ratio when the stent

is installed in a patient. Referring now to FIGS. 43- 45, stents **340, 350, 360** each have connectors **26** extending generally longitudinally between adjacent circumferential rings **28** and connecting to respective longitudinal strut portions **25** of longitudinally adjacent struts **24** of adjacent rings **28.** Connectors **26** are spaced apart and alternately connect every other pair of longitudinally adjacent struts connectors **26** are spaced apart and alternate every two or three strut pairs defining a more open cell structure. As shown in FIG. 43, one embodiment of a stent **340** may have connectors **26** that are substantially straight and may extend between the midsections of the longitudinal strut portions **25** of longitudinally adjacent struts **24.** Also, the midsection of longitudinal strut portions **25** may include a hole, space, or void **341,** thus further reducing the amount of material used. In some embodiments, void **341** may be provided adjacent the junction of connector **26** with longitudinal strut portion **25** and in alternate embodiments (*e.g.* FIG. 46) a void **341** may be provided at the midsection of every longitudinal strut portion. In this regard, the hole, space, or void permits the design of stent patterns utilizing even less material to, for example, further decrease the metal to surface area ratio. As shown in FIG. 44, an alternate embodiment of a stent **350** is shown having connectors **26** that are generally arcuate and extend between the midsections of the longitudinal strut portions **25** of longitudinally adjacent struts **24.** Referring to FIG. 45, another embodiment of a stent **360** is shown having connectors **26** that include an omega shaped feature **362** which permits expansion of connectors **26** in the longitudinal direction. In alternate embodiments, other geometries of connectors **26** may be used to accomplish the same purpose.

[0090] Stents **340, 350, 360,** shown in FIGS. 43-45, generally include a branch portion **30** similar to stent **320** (FIG. 41) including an outer ring **342,** and an inner ring **344.** Rings **342** and **344** are interconnected by a plurality of inner connectors **346.** Outer ring **344** is connected to elliptical transition members **348** by a plurality of outer connectors **352.** In these embodiments, outer connectors **352** include a subset of distal outer connectors **354, 356, 358** that extend from the distal side of outer ring **344** to the elliptical transition member on the distal side of branch portion **30.** Distal outer connectors **354, 356, 358** are generally S-shaped, zigzag-shaped, or wavelike. In this regard, the wavelike shape of distal outer connectors may be deformed to a greater extent and accommodate more expansion than, for example, a straight outer connector

design. In these embodiments, distal outer connectors **354, 356, 358** may generally accommodate large angles of rotation of the distal portion of branch portion **30** into the side branch vessel during implantation. For example, the distal petals **362, 364** may rotate more than 90° during implantation in the side branch vessel.

[0091] Referring to FIGS. 46 and 47, an alternate embodiment of a stent **370** is shown that is similar to stent **360**, described above, and generally includes a branch portion **30** including an outer ring **372**, and an inner ring **374**. Rings **372, 374** are generally curvilinear members and include undulation petals, prongs, or peaks **376**. In this embodiment outer ring **372** is generally less curvilinear than outer ring **342** of stents **340, 350, 360** described above. For example as shown in FIG. 46, outer ring **372** can be viewed as a series of interconnected connected W-shaped sections, wherein the legs of the W-shaped sections are straighter than the comparable sections of outer ring **342** described above. In this regard, the geometry of outer ring **372** may permit and/or facilitate different type of expansion characteristics of the branch portion **30** upon installation into a side branch vessel. In alternate embodiments, other geometries of outer ring **372** may be used.

[0092] Referring to FIG. 48, an alternate embodiment of a stent **380** is shown that is similar to stent **370**, described above, and generally includes a branch portion **30** including an outer ring **382**, and an inner ring **384**. Rings **382** and **384** are interconnected by a plurality of inner connectors **388**. Outer ring **382** is connected to elliptical transition members **390** by a plurality of outer connectors **392**. Rings **382, 384** are generally curvilinear members and include undulation petals, prongs, or peaks **394**. In this embodiment outer ring **382** generally includes the same number of peaks as inner ring **384**. For example, inner ring **384** generally includes eight major petals or peaks **396** extending toward and surrounding a central branch opening **397** and eight minor peaks **398** extending and alternating between major peaks **396**. Minor peaks **398** extend to a lesser extent toward central branch opening **397**. In operation, the intersection of outer connectors **392** with transition members **390** form a pivot point about which major petals **396** may unfold or pivot outward into the side branch vessel. In a preferred embodiment, the inner and outer connectors pivot together such that the major petals **396** open like a flower. Also, the minor peaks **398** of inner ring **384** may undergo deformation and expand when major petals pivot outward into the

side branch vessel. In this regard, the geometry of inner ring **384** may permit and/or facilitate different type of expansion characteristics of the branch portion **30** and may also provide for varying degrees of coverage or radial support of the side branch vessel wall upon installation into a side branch vessel. In alternate embodiments, other geometries of inner ring **384** may be used.

[0093] In all of the above embodiments, the branch portion **30** protrudes into the branch vessel when the stent is fully expanded. The branch portion upon expansion can extend into the branch vessel in different lengths depending upon the application. The amount of extension may vary in a range between about 0.1-10.0 mm. In one preferred embodiment, the length of extension is 1-3 mm. In another preferred embodiment, the length of extension is approximately 2 mm. In alternative embodiments, the amount of extension into the branch vessel may be variable for different circumferential segments of branch portion **30**. As shown in each of the embodiments, the branch portion is approximately 2.5 mm in width and about 2.5 - 3.0 mm in length. However, the branch portion can be dimensioned to accommodate varying size branch vessels. The branch portion can be formed of any tubular shape to accommodate the branch vessel, including, oval or circular, for example.

[0094] In general, a wide variety of delivery systems and deployment methods may be used with the aforementioned stent embodiments. For example, a catheter system may be used for insertion and the stent may be balloon expandable or self-expandable, or the stent may be balloon expandable and the branch portion self-expandable, or vice versa. Once the stent is in position in the main vessel and the branch portion is aligned with the side branch the stent can be expanded. If the stent is balloon expandable, the stent may be expanded with a single expansion or multiple expansions. In particular, the stent can be deployed on a stent delivery system having a balloon catheter and side sheath as described, for example, in U.S. Patent Nos. 6,325,826 and 6,210,429, the entire contents of which are incorporated herein by reference. In one preferred embodiment, a kissing balloon technique may be used, whereby one balloon is configured to expand the stent and the other balloon is configured to extend branch portion **30**. After the main portion of the stent is expanded in the main vessel, the stent delivery system may be removed and a second balloon may be passed through the side hole in the branch portion and expanded to

expand the branch portion of the stent. In an alternate embodiment, the same balloon may be inserted in the main vessel inflated, deflated, retracted and inserted into the branch vessel, and then reinflated to expand branch portion **30** and cause it to protrude into the branch vessel. Alternatively, the stent can be delivered on two balloons and the main portion and the branch portion can be expanded simultaneously. As needed, the branch portion can be further expanded with another balloon or balloons. Yet another alternative is to use a specially shaped balloon that is capable of expanding the main and branch portions simultaneously. The stent can also be deployed with other types of stent delivery systems. Alternatively, the stent, or portions of the stent, can be made of a self-expanding material, and expansion may be accomplished by using self-expanding materials for the stent or at least branch portion **30** thereof, such as Nitinol, Cobalt Chromium, or by using other memory alloys as are well known in the prior art.

[0095] The construction and operation of catheters suitable for the purpose of the present invention are further described in U.S. Patent Application No. 09/663,111, filed September 15, 2000, which is a continuation-in-part of U.S. Patent Application No. 09/614,472, filed July 11, 2000, which is a continuation-in-part of U.S. Patent Application Nos. 09/325,996, filed June 4, 1999, and 09/455,299, filed December 6, 1999, the disclosures of all of which are incorporated herein by reference. It should be noted that the catheters taught in the above applications are exemplary, and that other catheters that are suitable with the stents of the subject application are included within the scope of the present application. In alternative embodiments, catheters without balloons may be used. For example, if the stent is comprised of memory alloy such as Nitinol or Cobalt Chromium, or is a mechanically self-expanding stent, balloons are not necessarily included on the catheters. Furthermore, any other catheter, including ones that are not disclosed herein, may be used to position stents according to the present invention.

[0096] Referring now to FIGS. 25-28, illustrations of the steps of one example of a method for employing a stent according to the invention are shown. By way of example, the method is depicted utilizing stent **12**. Methods for positioning such a catheter system within a vessel and positioning such a system at or near a bifurcation are described more fully in co-pending U.S. Patent Application No. 10/320,719 filed

on December 17, 2002, which is incorporated herein by reference in its entirety. As shown in FIG. 25, a catheter system **120** is positioned proximal to a bifurcation, using any known method. A branch guidewire **122** is then advanced through an opening in the stent and into the branch vessel **4**, as shown in FIG. 26. In a preferred embodiment, the opening may be a designated side branch opening, such as an opening formed by the absence of some connectors **26**, as described above. Branch portion **30** is adjacent the opening. As shown in FIG. 27, if the side sheath **124** is attached to the main catheter **120**, the main catheter **120** is advanced along with the side catheter **124**. Alternatively, if the side sheath **124** is separate from to the main catheter **120**, the second catheter or side sheath **124** is then advanced independently through the opening in the stent and into the branch vessel. Branch portion **30** is positioned over a portion of the lumen of the branch vessel **4** as the side sheath **124** is inserted into branch vessel **4**. Referring to FIG. 28, a first balloon **126** located on main catheter **120** is then expanded, causing expansion of the stent body, and a second balloon **128** located on the second catheter or side sheath **124** is also expanded, causing branch portion **30** to be pushed outward with respect to the stent body, thus providing stent coverage of at least a portion of the branch vessel. The balloons are then deflated and the catheter system and guidewires are then removed.

[0097] Referring now to FIGS. 29-31, illustrations of the steps of another method for employing a stent of the present invention is shown. By way of example, the method is depicted utilizing stent **12**. The depicted method may be accomplished using a catheter system having a main catheter **131** including a herniated balloon **135** (FIG. 32). In particular, the stent can be deployed on a stent delivery system having a herniated balloon as described, for example, in U.S. Patent Application No. 60/488,006, filed July 18, 2003, the entire contents of which are incorporated herein by reference. As shown in FIG. 29, the catheter **131** includes a balloon **135** that has a protruding portion **137** that protrudes outwardly from the cylindrical outer surface **134** of the balloon.

[0098] Referring to Fig. 32, the herniated balloon **135**, shown in an expanded state, has a generally cylindrical shape and the protruding portion **137** can be any appendage or integral portion of the balloon that moves outwardly from the outer surface **134** of the balloon upon inflation, in accordance with the principles of the

invention. In a preferred embodiment, the protruding portion **137** is a portion of the balloon wall that has greater expandability than other portions of the balloon wall that retain a generally cylindrical shape. In another embodiment, protruding portion **137** may be a solid structure attached to the balloon wall. The protruding portion **137** can have any shape desirable to effect deployment of branch portion **30**. In one preferred embodiment, protruding portion **137** has a hemispherical shape. In another preferred embodiment, protruding portion **137** has an ovoid shape. In use, the stent **12** is crimped onto the balloon **135** so that the protruding portion **137** is positioned at the branch portion. As shown, the protruding portion **137** is positioned adjacent or alongside the radially inward side of branch portion **30**. The herniated balloon **135** is used to expand the branch portion **30** and/or deploy the outwardly deployable structure of stent **12** by applying a force in the laterally outward direction to the expandable elements by deflecting these elements toward the side branch **4**. The protruding portion **137** may be located at any position along the length of the balloon. For example, it can be located on the middle 1/3 of the stent.

[0099] In one embodiment, the balloon may be constructed of composite materials. For example, a combination of elastomeric and semi to non compliant materials such as urethane, silicone, and latex, (Elastomeric) polyethylene hytrel pebax polyaryletherketone, polyoxymethylene, polyamide, polyester thermoplastic polyetheretherketone and polypropylene (semi to non compliant), may be used. The balloon may also be constructed by combining the above-mentioned materials with woven textiles such as Kevlar, silk cotton, wool, etc. In this construction, a textile is wound or woven onto a rod that has the shape of the desired herniated balloon and the polymer is then extruded or dip coated over the rod. The composite is cured, heat set or adhesively fused together. The rod is then removed and the remaining shape is a herniated balloon. The balloon can also be constructed by adding an appendage to a conventional balloon by using a molded collar or adhesively attaching an object to the surface of the balloon or by using a mound of adhesive to create the herniation or protruding portion. In an alternate embodiment, the balloon can be constructed by molding three small balloons and attaching them in tandem with the center balloon being round in shape. The balloon would share a common inflation port. When the balloon is inflated the center balloon becomes the herniation.

[00100] Referring again to FIGS. 29-31, protruding portion **137** may be configured to fit directly into an opening in the stent. As shown in FIG. 29, catheter **131** is advanced over a guidewire **133** and positioned proximal to the bifurcation. As shown in FIG. 30, the catheter is advanced until the protruding portion **137** of the balloon is positioned at the bifurcation. In one embodiment, protruding portion **137** protrudes outwardly from catheter **131** enough so that it actually comes into contact with the bifurcation, thus providing a method of alignment with the branch vessel **4**. Finally, as shown in FIG. 31, balloon **135** is expanded, which simultaneously causes the stent to expand and branch portion **30** to be pushed toward the branch vessel **4**. Upon inflation of the balloon, the herniated portion **137** expands and extends through the branch portion **30** toward the side branch to open the entrance of the occluded side branch artery.

[00101] In an alternative method, the stent can be delivered using a herniated balloon and a dual lumen delivery system. This system can include a main catheter defining a first lumen with concentric guidewire lumen and balloon inflation lumen, a herniated balloon, as described above, on the main catheter, a side sheath with a guidewire lumen, and a stent. The stent is crimped over the main catheter, balloon and side sheath with the side sheath exiting the stent through a branch opening or side hole. The distal end of the side sheath is used for aligning the stent branch opening with the branch vessel **4**.

[00102] In another embodiment, the appendage or herniation may be located on a second catheter or side sheath of the delivery system, such as the system **138** depicted in FIG. 33. In this case, the system is a two-balloon system. The smaller balloon **140** can be positioned in the stent in a similar manner as the herniation. The appendage or herniation may have an inflation lumen **141** and a lumen for receiving a guidewire **142** for locating the branch vessel **4**.

[00103] One particular application for the use of a stent with a branch portion **30** such as the one described above is for localized drug delivery. As was discussed hereinabove, restenosis, including in-stent restenosis, is a common problem associated with medical procedures involving the vasculature. Pharmaceutical agents have been found to be helpful in treating and/ or preventing restenosis, and these are best delivered locally to the site of potential or actual restenosis, rather than systemically.

[00104] As used herein, the term "preventing" includes stopping or reducing the occurrence or severity of a disease or condition or the symptoms of the disease or condition.

[00105] As used herein, the term "treating" includes substantially reducing the severity of a disease or condition or the symptoms of the disease or condition, or substantially reducing the appearance of a disease or condition or the symptoms of the disease or condition. The term "treating" includes substantially completely abolishing a disease or condition or the symptoms of the disease or condition. The term "treating" also encompasses preventing, stopping, or reducing the occurrence or severity of a disease or condition or the symptoms of the disease or condition.

[00106] When—as with anti-restenosis drugs, for example—a drug is useful primarily at a particular body site, systemic administration is not necessary and is often undesirable. For instance, systemic administration of drugs often results in undesirable side effects. Also, it is difficult to achieve constant drug delivery to a site needing treatment using systemic delivery methods. Drugs administered systemically often cycle through concentration peaks and valleys, resulting in time periods of toxicity and ineffectiveness. In contrast, drugs delivered in a localized manner can be delivered at a high concentration at the site(s) where treatment is needed, while minimizing the systemic concentration of the drug, thus minimizing or eliminating side effects. Additionally, localized delivery facilitates the maintenance of appropriate drug levels at the treatment site, with minimal undesired fluctuation.

[00107] Stents according to the present invention may have one or more drug depots on and/or in the stent wall. As used herein, the term "depot" describes a store of at least one drug designed to retain and thereafter release the drug(s). According to current technology, materials incorporating drug(s) are often associated with stents by coating the drug-containing material(s) onto the walls of the stents. Thus, "coating" is referred to and used herein in describing the depot(s), but this use is solely for convenience of explanation and is in no way limiting, and other methods of associating drug(s) with stents that are currently available or that may become available are specifically contemplated. As another non-limiting example, as is discussed further hereinbelow, stents may be "seeded" with genetically engineered cells that secrete or otherwise release drug(s). As yet another non-limiting example,

biocompatible polymers incorporating drug(s) may be molded into a solid mass of a desired size and shape and attached to the stent using pharmaceutically acceptable methods.

[00108] The term "depot" refers generally to an area of a stent that is coated or otherwise associated with drug(s) or a material incorporating drug(s). Any given depot is generally discrete from other depots. For example, in certain embodiments, a depot may consist of a discrete mass of material incorporating drug(s). As another example, because the walls of stents according to the present invention comprise open spaces, a depot may also include spaces. A depot may include open spaces, for example, in embodiments where drug(s) or a material incorporating drug(s) is coated or seeded onto a stent to form the depot. One depot may abut, or be adjacent to a second depot, but the second depot will generally have different drug(s) and/or different concentration(s) of drug(s), as is discussed in further depth hereinbelow.

[00109] It will be understood that depot(s) of stents according to the present invention can be "on" or "in" the stent walls. For example, where it is desired to release drugs(s) primarily to the cells of the vessel walls at the site of placement of a stent, it may be desirable to coat, attach a drug-containing mass, or otherwise associate drug(s) with only the outer side of the stent wall. As another example, when it is desired to deliver drug(s) to an organ, tissue, or region of the body downstream from a stent, it may be desirable to coat, attach a drug-containing mass, or otherwise associate drug(s) with only the inner side of the stent wall. In still other embodiments, it may be desirable to coat, attach a drug-containing mass, or otherwise associate drug(s) with the inner side of the stent wall, the outer side of the stent wall, and/or the portions of the stent wall that face inward to the open spaces within the wall.

[00110] The terms "drug," "drug compound," and "pharmaceutical agents" are used interchangeably herein, unless stated otherwise. These terms are meant to be construed broadly, to mean pharmaceutically acceptable substances (*i.e.*, substances that are safe for use in the body of a mammal such as a human) and that have some biological effect on cells of the body. The terms also include substances that are being tested for safety for use in the body of a mammal such as a human and/or to determine whether (or what) biological effect they have on cells of the body.

Examples of types of molecules that may be drugs as the term is defined herein include, but are not limited to, proteins and peptides, small molecules, antibodies, multi-cyclical molecules, macrolides, and nucleic acids. The general and specific examples provided herein, as well as similar substances, are included in the term "drugs" according to the present invention.

[00111] Depots of stents according to the present invention are capable releasing, or eluting, the stored drug(s). Hence, the depots of the present invention can be made of any material that can entrap, encapsulate, adhere, or otherwise retain and thereafter release the stored drug(s). Depots of stents according to the present invention are preferably capable of controllably releasing drug(s). Hence, the depots of the present invention are preferably made of any material that can entrap, encapsulate, adhere or otherwise retain and controllably release the stored drug(s).

[00112] The phrases "controllably release", "controllable release," and "controllably releasing" are used herein to describe a release of drug(s) at a predetermined rate and duration under selected conditions. Slow release is one form of controllable release.

[00113] In certain preferable embodiments, depots of the present invention comprise one or more biocompatible polymer(s) loaded with drug(s). In certain embodiments, the biocompatible polymer utilized minimizes irritation to the wall of the lumen where the stent is implanted. Methods for incorporating biocompatible polymers loaded with drug(s) into or onto stents generally involve coating the stent with the polymer(s) and are well known in the art. *See, e.g.,* U.S. Pat. No. 5,679,400.

[00114] Several configurations for loading drug(s) into biocompatible polymers are envisaged by the present invention. The drug(s) may be, for example, molded into the polymer, entrapped or encapsulated within the polymer, covalently attached to the polymer, physically adhered to the polymer, or otherwise incorporated into the biocompatible polymer.

[00115] The biocompatible polymer may be, for example, either a biostable polymer or a biodegradable polymer, depending on factors such as the desired rate of release or the desired degree of polymer stability under physiological conditions.

[00116] Biodegradable polymers that are usable in the context of the present invention include, without limitation, poly(L-lactic add), polycaprolactone, poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(D,L-lactic acid), poly(glycolic acid-co-trimethylene carbonate), polyphosphoester, polyphosphoester urethane, poly(amino acids), cyanoacrylates, poly(trimethylene carbonate), poly(iminocarbonate), copoly(ether-esters) (e.g. PEO/PLA), polyalkylene oxalates, polyphosphazenes and biomolecules such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid.

[00117] Biostable polymers that are usable in the context of the present invention include, without limitation, polyurethanes, silicones, polyesters, polyolefins, polyisobutylene, ethylene-alphaolefin copolymers; acrylic polymers and copolymers, vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl ethers, such as polyvinyl methyl ether; polyvinylidene halides, such as polyvinylidene fluoride and polyvinylidene chloride; polyacrylonitrile, polyvinyl ketones; polyvinyl aromatics, such as polystyrene, polyvinyl esters, such as polyvinyl acetate; copolymers of vinyl monomers with each other and olefins, such as ethylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins, and ethylene-vinyl acetate copolymers; polyamides, such as Nylon 66 and polycaprolactam; alkyd resins; polycarbonates; polyoxymethylenes; polyimides; polyethers; epoxy resins; polyurethanes; rayon; rayon-triacetate; cellulose, cellulose acetate, cellulose butyrate; cellulose acetate butyrate; cellophane; cellulose nitrate; cellulose propionate; cellulose ethers; and carboxymethyl cellulose.

[00118] In certain other embodiments, depot(s) on or in stents according to the present invention comprise liposomes into which drug(s) have been encapsulated or entrapped. Methods for incorporating liposomes loaded with drug(s) into or onto stents generally involve coating the stent with the polymer(s) and are known in the art. *See, e.g.,* Kallinteri P. *et al.* "Dexamethasone incorporating liposomes: an in vitro study of their applicability as a slow releasing delivery system of dexamethasone from covered metallic stents," *Biomaterials* 23(24): 4819-26 (2002). In yet other embodiments, depot(s) depot(s) on or in stents according to the present invention comprise genetically engineered cells that secrete or otherwise release desired drug(s),

e.g., therapeutic protein(s). Methods for incorporating genetically engineered cells into or onto stents generally involve seeding the cells onto the stent and are known in the art. *See, e.g.,* Dichek, D. A. *et al.,* "Seeding of Intravascular Stents With Genetically Engineered Endothelial Cells", *Circulation,* 80: 1347-1353 (1989); Flugelman M.Y. *et al.,* "Genetically engineered endothelial cells remain adherent and viable after stent deployment and exposure to flow in vitro," *Circ Res.,* 70: 348-54 (1992).

[00119] One or more depots may be present at any location in or on the walls of stents according to the present invention. Depot(s) may be utilized with any and all stents according to the present invention. Depot(s) may be present in or on the wall of the main vessel portion of stents according to the present invention. Similarly, depot(s) may be present in or on the wall of the branch portion of stents according to the present invention. The position of depot(s) depends on desired site(s) of highest concentration of drug delivery.

[00120] The size of depot(s) on or in stents of the present invention depends on various parameters, such as the material of which the stent body is fabricated, the permeability of the stent body and the depot, the efficacy of the depot in retaining the drug(s), the concentration of the drug(s), and the desired rate and duration of release of the drug(s). Depot(s) may extend around the entire, or only a portion of, the circumference of main vessel portions of stents according to the present invention. Likewise, depot(s) may extend longitudinally for all or only a portion of the length of main vessel portions of stents according to the present invention. With regard to branch portions of stents according to the present invention, depot(s) may cover all or only a portion of the walls, or may be in all or only a portion of the walls.

[00121] When it is desired to increase the overall volume of a depot, it may often be preferable to increase the length and/or width of the depot, rather than its thickness, or depth. In other words, it may often be preferable to increase the size of a depot along or within the wall of a stent, rather than extending the depot farther into the lumen of the stent. Depot(s) that extend too far into the lumen of a stent may impede fluid flow through the stent, and depots that are too thick on the outside wall may deform the stent into the vessel, also impeding fluid flow. However, it may be desirable to concentrate a large volume of depot in a small surface area, to maximize

drug concentration to a small section of vessel. Contrariwise, it may in other instances be desirable to have drug(s) released along a large section of vessel, in which cases it may be desirable to use a depot that has a large surface area along or within a wall of the stent.

[00122] Thus, the length, width, and thickness of a depot are variables that can be tailored according to the desired drug distribution and the size of the main and branch vessels to be treated. For example, a depot that is thick enough to impede fluid flow in a narrow vessel may be an optimal thickness for a larger vessel.

[00123] Additionally, the concentration of drug(s) in a depot can be varied according to the desired rate of elution of the drug from the depot and the desired concentration of the drug in the local area of the depot. Thus, the parameters of depot length, width, and thickness and drug concentration can be varied to tailor depots to elute the desired concentration of drug(s) to the desired area(s) in vessels of varying sizes.

[00124] Non-limiting examples of anti-restenosis drugs that may be incorporated into depot(s) in or on stents according to the present invention include anticoagulant agents, antiproliferative agents, antimigratory agents, antimetabolic agents, anti-inflammatory agents, and immunosuppressive substances, and combinations thereof. Particularly useful anti-restenosis drugs include paclitaxel, rapamycin, and HDAC inhibitors. Examples of histone deacetylase (HDAC) inhibitors, which are efficient inhibitors of smooth muscle cell (SMC) proliferation, include, without limitation, hydroxamic acids such as trichostatin A (TSA), suberoyl anilide hydroxamic acid (SAHA), oxamflatin, m-carboxycinnamic acid bishydroxamide (CBHA), cyclic hydroxamic acid-containing peptide 1 (CHAP1), cyclic hydroxamic acid-containing peptide 31 (CHAP31), suberic bishydroxamate (SBHA), pyroxamide, and scriptaid. Further details pertaining to an HDAC inhibitors, their use, and stents incorporating same are disclosed in a U.S. Provisional Patent Application assigned to a common assignee of the present invention, filed July 24, 2002, Attorney Docket No. 03/23768, entitled "STENTS CAPABLE OF CONTROLLABLY RELEASING HISTONE DEACETYLASE INHIBITORS," incorporated by reference herein in its entirety.

[00125] In addition to anti-restenosis drugs, stents according to the present invention can also be used as vehicles for localized delivery of other drugs. As a non-limiting example, stents of the present invention are particularly useful in for localized delivery of anti-thrombotic drugs. Thrombosis (the formation of a thrombus, or blot clot) sometimes occurs in association with medical procedures involving the vasculature. For example, thrombosis may result from physical injury of an arterial wall by a vascular interventional procedure such as percutaneous transluminal coronary angioplasty ("PTCA"; a type of balloon angioplasty) or coronary bypass surgery. Although thrombosis can result in death, the procedures which may have thrombosis as a side effect are themselves are life-saving and widely used. Additionally, thrombosis may also result from progression of a natural disease, such as atherosclerosis. Accordingly, administration of anti-thrombotic drugs to patients who have undergone vascular procedures is often desirable.

[00126] Many anti-thrombotic drugs are known in the art. Non-limiting examples include aspirin (acetylsalicylic acid), prostaglandin E_1, selective thromboxane A_2 inhibitors, selective thrombin inhibitors, platelet receptor GPIIb/IIIa blockers, tissue plasminogen activator, streptokinase, heparin, hirudin, bivalirudin, and kistrin and other platelet and/or thrombin inhibitors. As with anti-restenosis drugs, administration of anti-thrombotics locally to the site of potential thrombosis is usually vastly preferable to systemic administration.

[00127] Additional, non-limiting examples of types of drugs that may be incorporated into depot(s) in or on stents according to the present invention include antineoplastic, antimitotic, antiplatelet, antifibrin, antithrombin, antibiotic, antioxidant, and antiallergic substances as well as combinations thereof.

[00128] Depots for use in accordance with the present invention may include one or more different drug(s). For example, it will often be desirable to include two or more drugs that have additive, or even synergistic effects. Where more than one drug is incorporated into a single depot, it will be generally preferred to incorporate drugs that will not interfere with, degrade, destabilize, or otherwise interfere with one another. However, in some cases in may be desirable to include a first drug along with a second drug that reduces or alters the activity of the first drug in a desired manner. In the same manner, different depots may include different drugs, or

different concentrations of the same drug. The many possible permutations allow for great flexibility in treatment.

[00129] Stents according to the present invention can be used as vehicles for localized delivery of drugs to cells of the walls of both the main and branch vessels at the location of the stent. Drugs that are particularly suitable for treatment of cells in the immediate area of the stent include anti-restenosis and anti-thrombotic drugs. If desired, different concentrations of drugs, or different drugs, may be included in depot(s) located in or on different areas of the stent walls. For example, it may be desirable to treat the cells of the main vessel with a first drug, combination of drugs, and/or concentration of drug(s) and to treat the cells of the branch vessel with a second, different, drug, combination of drugs, and/or concentration of drug(s). As another example, it may be desirable to maintain a high concentration of anti-restenosis drug(s) near the bifurcation of the vessels. As yet another non-limiting example, it may be desirable to maintain a high concentration of anti-restenosis drug(s) at the three open ends (two on the main portion and one on the branch portion) of the stent. It will be appreciated by one skilled in the art upon reading the present disclosure that many combinations of two or more depots are possible within the spirit and scope of the present invention.

[00130] Stents according to the present invention can be used as vehicles to deliver drug(s) to an organ, tissue, or region of the body downstream from the stent. For example, stents according to the present invention may be positioned in an artery that supplies blood to an organ, such as the heart, in a location close to that organ. Drug(s) that elute from the depot(s) in or on the stent may be carried by the blood flow to the organ. In this way, localized delivery to tissues, organs, and body regions can be achieved. Using stents according to the present invention, a first drug, combination of drugs, and/or concentration of drug(s), may be delivered to an organ, tissue, or region downstream from the main portion of the stent while a second, different, drug, combination of drugs, and/or concentration of drug(s) is delivered to an organ, tissue, or region downstream from the branch portion of the stent. This differential delivery can be accomplished by locating a depot having a first drug, combination of drugs, and/or concentration of drug(s) in or on an area of the main portion of the stent that is not contacted by blood flowing through the branch vessel,

and locating a second depot having a second, different, drug, combination of drugs, and/or concentration of drug(s) in or on the branch portion of the stent. It will be appreciated by one skilled in the art upon reading the present disclosure that many combinations of two or more depots are possible within the spirit and scope of the present invention.

[00131] Specific, and non-limiting, examples of drugs that may be incorporated into depot(s) in or on stents according to the present invention include the following drugs. Examples of antineoplastic and/or antimitotic drugs include docetaxel (*e.g.*, Taxotere® from Aventis S.A., Frankfurt, Germany) methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, doxorubicin hydrochloride (*e.g.*, Adriamycin® from Pharmacia & Upjohn, Peapack N.J.), and mitomycin (*e.g.*, Mutamycin® from Bristol-Myers Squibb Co., Stamford, Conn.). Examples of antiplatelet, anticoagulant, antifibrin, and antithrombin drugs include sodium heparin, low molecular weight heparins, heparinoids, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist antibody, recombinant hirudin, and thrombin inhibitors such as Angiomax™ (Biogen, Inc., Cambridge, Mass.). Examples of cytostatic or antiproliferative drugs include angiopeptin, angiotensin converting enzyme inhibitors such as captopril (*e.g.*, Capoten® and Capozide® from Bristol-Myers Squibb Co., Stamford, Conn.), cilazapril or lisinopril (*e.g.*, Prinivil® and Prinzide® from Merck & Co., Inc., Whitehouse Station, N.J.); calcium channel blockers (such as nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, histamine antagonists, lovastatin (an HMG-CoA reductase inhibitor, brand name Mevacor® from Merck & Co., Inc., Whitehouse Station, N.J.), monoclonal antibodies (such as those specific for Platelet-Derived Growth Factor (PDGF) receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitors, suramin, serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. An example of an antiallergic agent is permirolast potassium. Other therapeutic substances or agents that may be used include alpha-interferon and dexamethasone. The preventative and treatment properties of the foregoing therapeutic substances or agents are well-known to those of ordinary skill in the art.

[00132] The present invention also provides kits comprising a stent or stents according to the present invention. In addition to a stent or stents, a kit according to the present invention may include, for example, delivery catheter(s), balloon(s), and/or instructions for use. In kits according to the present invention, the stent(s) may be mounted in or on a balloon or catheter. Alternatively, the stent(s) may be separate from the balloon or catheter and may be mounted therein or thereon prior to use.

[00133] While the invention has been described in conjunction with specific embodiments and examples thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art upon reading the present disclosure. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

WHAT IS CLAIMED IS:

1. A bifurcation stent, comprising:

a tubular member having an inner diameter and an outer diameter defining a wall therebetween, the wall having a geometrical configuration defining a pattern; and

an expandable branch structure formed in the wall of the tubular structure and interrupting the wall pattern, the expandable branch structure having a first ring connected to the tubular member and a second ring connected to the first ring, the first ring being concentric with the second ring,

wherein the second ring substantially surrounds and defines a central branch opening,

wherein the first ring and the second ring are movable from an unexpanded configuration to an expanded configuration, in the unexpanded configuration the first and second rings are disposed along the wall and in the expanded configuration the first and second rings extend outwardly from the tubular member, and

wherein an auxiliary access opening is defined between the first and second rings to provide access to a branch vessel in the unexpanded condition, the auxiliary access opening being larger than the central branch opening in the unexpanded configuration.

2. The stent according to claim 1, wherein the tubular member has a longitudinal axis and the expandable branch structure is disposed substantially perpendicular to the longitudinal axis in the expanded configuration.

3. The stent according to claim 1, wherein the tubular member comprises a plurality of undulating rings disposed along the longitudinal axis and the undulating rings are connected by connectors.

4. The stent according to claim 1, wherein the first and second rings have a common axis disposed substantially perpendicular to the longitudinal axis in the unexpanded configuration.

5. The stent according to claim 1, wherein the branch structure includes a transition ring.

6. The stent according to claim 5, wherein the transition ring comprises a discontinuous portion.

7. The stent according to claim 5, wherein at least one omega shaped connecting member extends between the transition ring and the wall pattern.

8. The stent according to claim 6, wherein at least one connecting member extends through the discontinuous portion and connects the first ring to a portion of the wall pattern outside the extendible branch structure.

9. The stent according to claim 8, wherein the at least one connecting member connects the first ring to an omega shaped strut portion of the wall pattern outside the extendible branch structure.

10 The stent according to claim 5, wherein the second ring is connected to the first ring by a plurality of inner connectors.

11. The stent according to claim 10, wherein the first ring is connected to the transition ring by a plurality of outer connectors.

12. The stent according to claim 11, wherein at least one of the outer connectors is a generally undulating curvilinear member extending toward the center of the branch opening.

13. The stent according to claim 11, wherein the inner and outer connectors are generally straight members and extend toward the center of the branch opening.

14. The stent according to claim 13, wherein the first and second rings are generally continuous undulating curvilinear members and include undulation peaks extending toward the central branch opening.

15. The stent according to claim 11, wherein the intersection of each outer connector with the transition ring forms a pivot point about which an undulation peak may pivot outward in the expanded configuration.

16. The stent according to claim 1, wherein the first and second rings are generally continuous curvilinear members and include undulation peaks, wherein the undulation peaks of the second ring have a radius of curvature of about 0.025 mm to about 0.225 mm.

17. The stent according to claim 15, wherein the undulation peaks of the second ring have a radius of curvature of about 0.125 mm to about 0.225 mm.

18. A bifurcation stent, comprising:

a tubular member having an inner diameter and an outer diameter defining a wall therebetween, the wall having a geometrical configuration defining a pattern; and

an expandable branch structure formed in the wall of the tubular structure and interrupting the wall pattern, the expandable branch structure having a first ring

connected to the tubular member and a second ring connected to the first ring, the first ring being concentric with the second ring,

wherein the second ring substantially surrounds and defines a central branch opening,

wherein the first ring and the second ring are movable from an unexpanded configuration to an expanded configuration, in the unexpanded configuration the first and second rings are disposed along the wall and in the expanded configuration the first and second rings extend outwardly from the tubular member, and

wherein the first and second rings are generally continuous curvilinear members and include undulation peaks, wherein the undulation peaks of the second ring have a radius of curvature of about 0.025 mm to about 0.225 mm.

19. The stent according to claim 18, wherein the undulation peaks of the second ring have a radius of curvature of about 0.125 mm to about 0.225 mm.

20. A bifurcation stent, comprising:

a tubular member having an inner diameter and an outer diameter defining a wall therebetween, the wall having a geometrical configuration defining a pattern; and

an expandable branch structure formed in the wall of the tubular structure and interrupting the wall pattern, the expandable branch structure having a first ring connected to the tubular member and a second ring connected to the first ring, the first ring being concentric with the second ring,

wherein the second ring substantially surrounds and defines a central branch opening,

wherein the first ring and the second ring are movable from an unexpanded configuration to an expanded configuration, in the unexpanded configuration the first and second rings are disposed along the wall and in the expanded configuration the first and second rings extend outwardly from the tubular member,

wherein the branch structure includes a transition ring,

wherein the second ring is connected to the first ring by a plurality of inner connectors and the first ring is connected to the transition ring by a plurality of outer connectors, and

wherein at least one of the outer connectors is a generally undulating curvilinear member extending toward the center of the branch opening.

FIG. 1

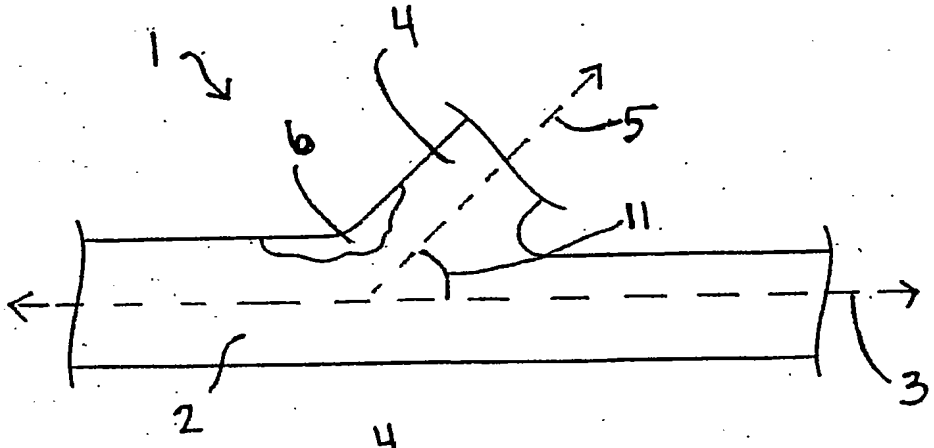


FIG. 2

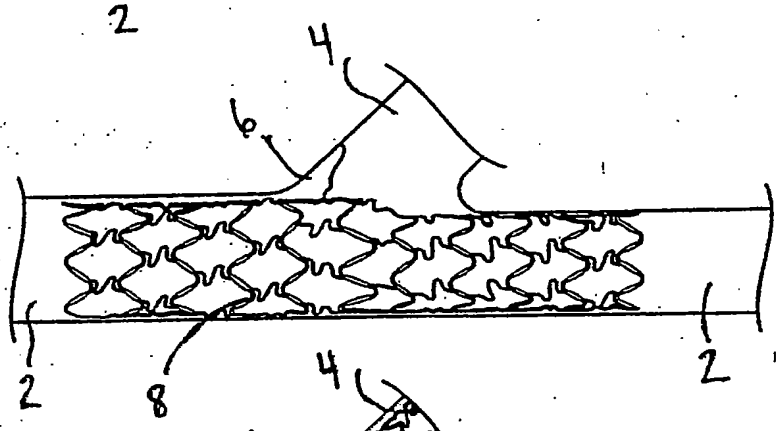


FIG. 3

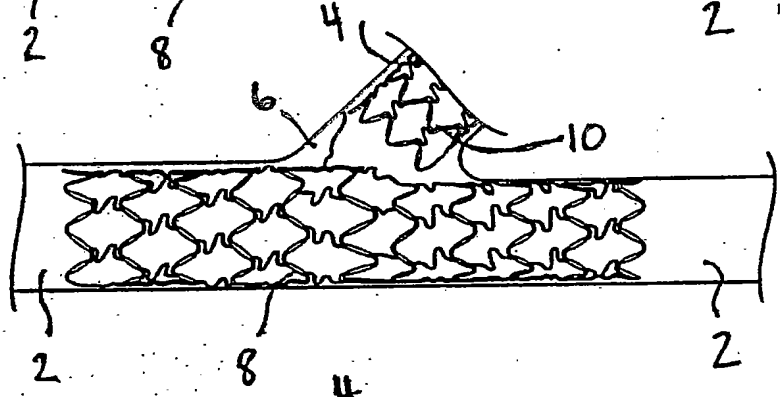
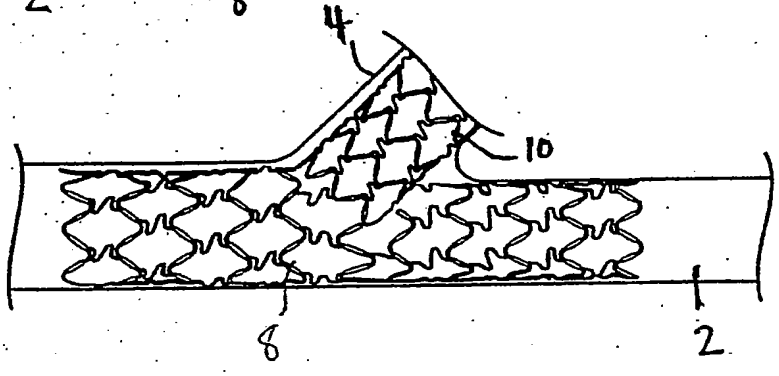


FIG. 4



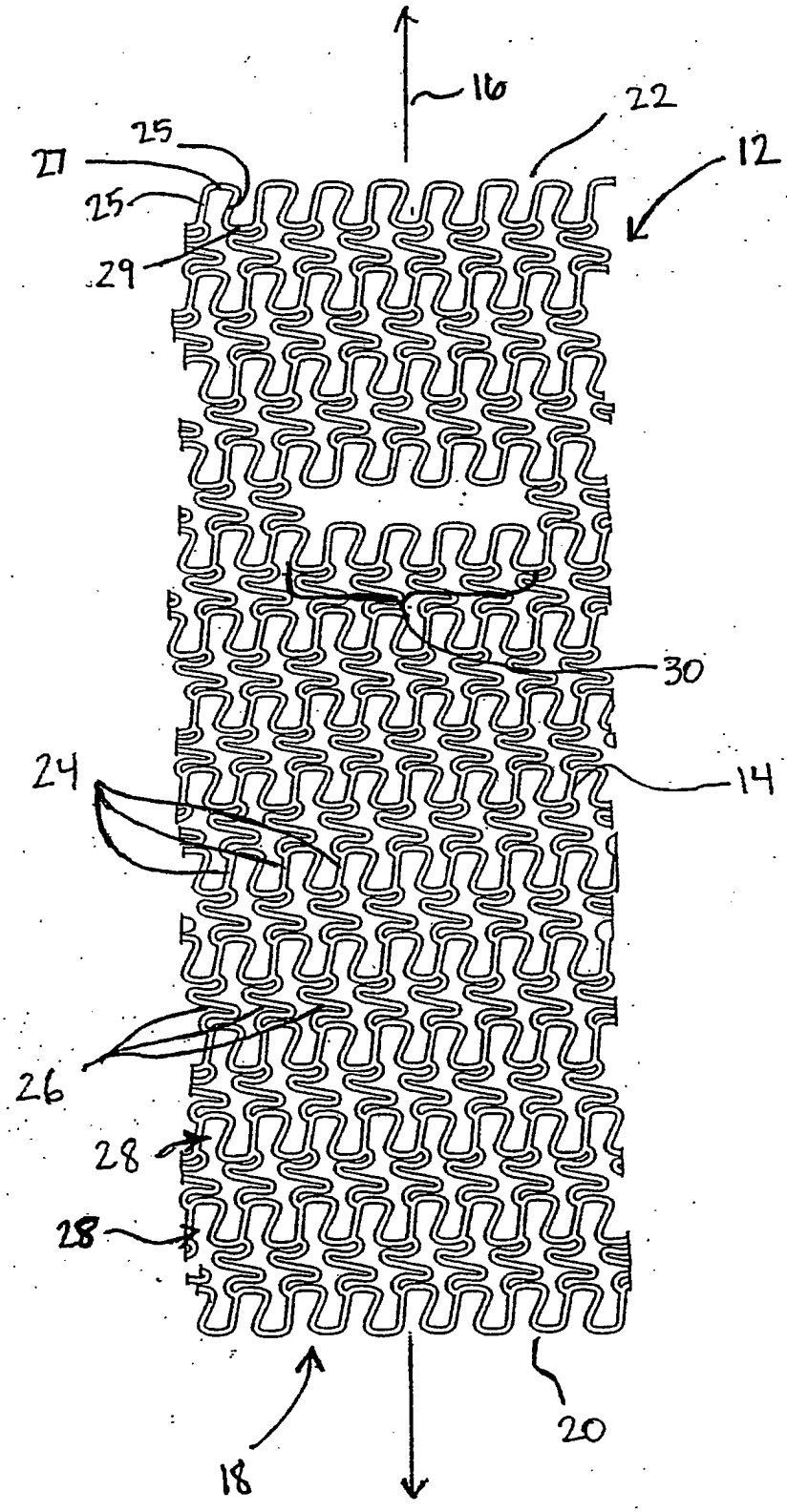


FIG. 5

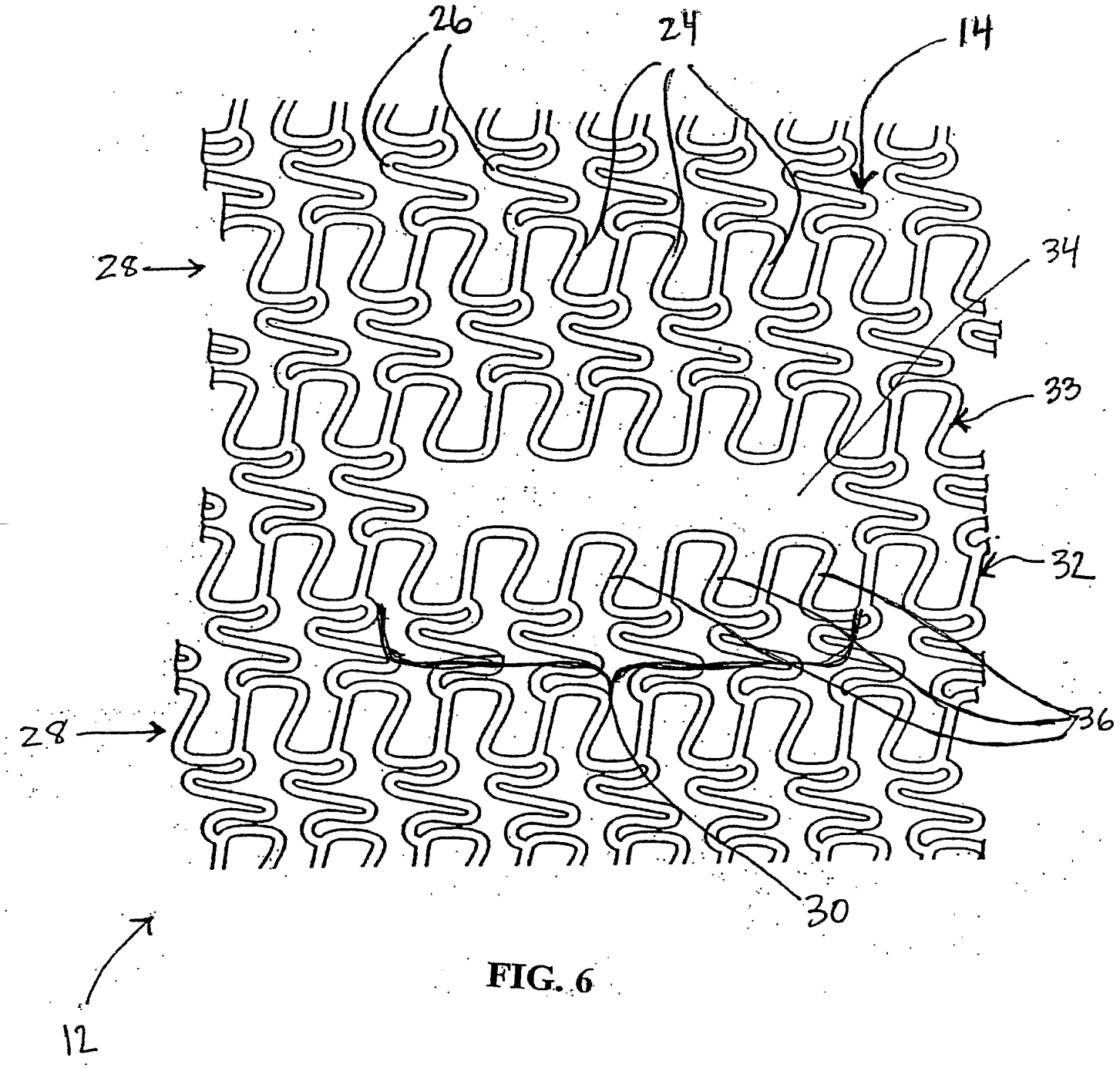


FIG. 6

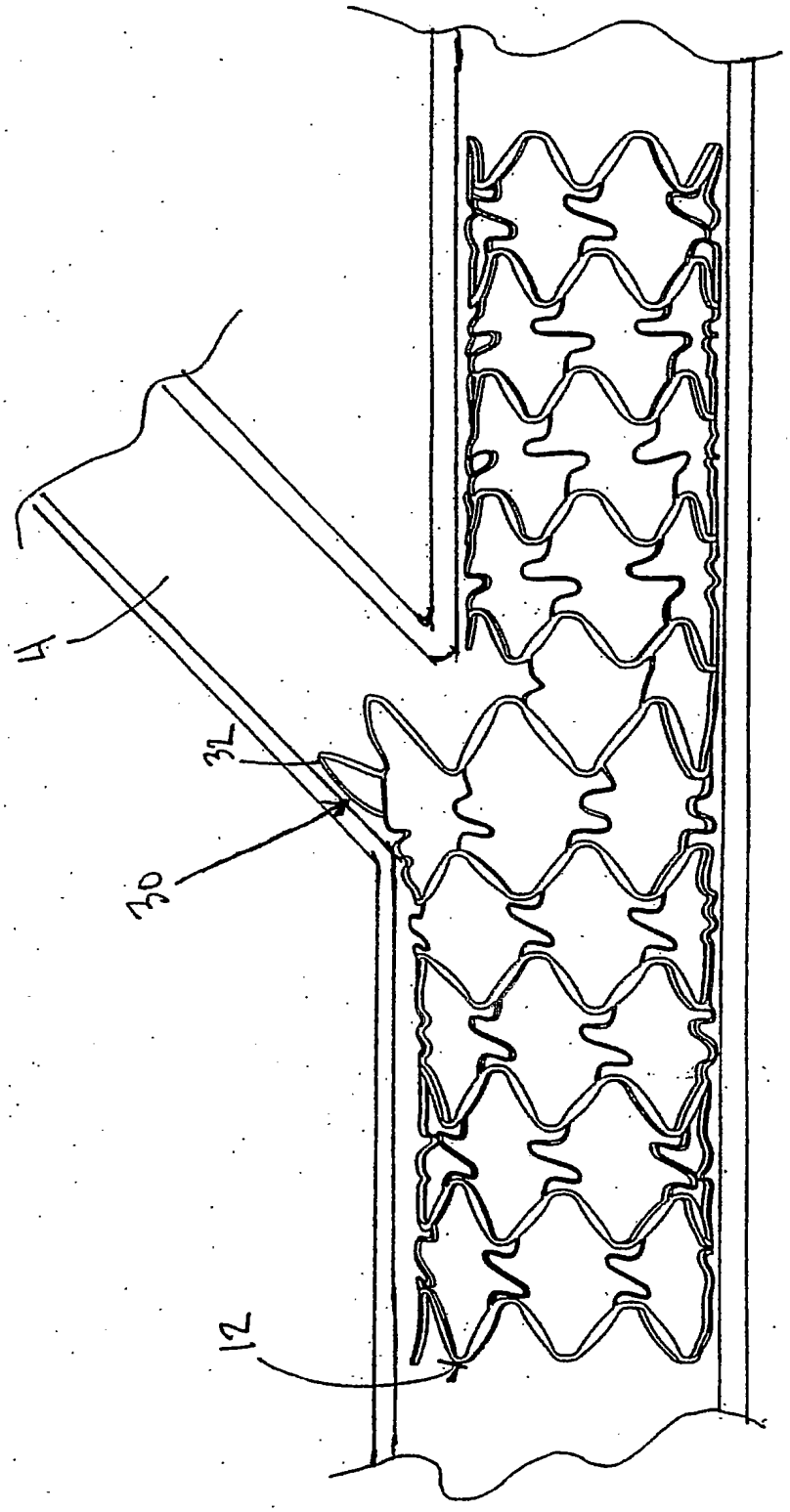


FIG. 7

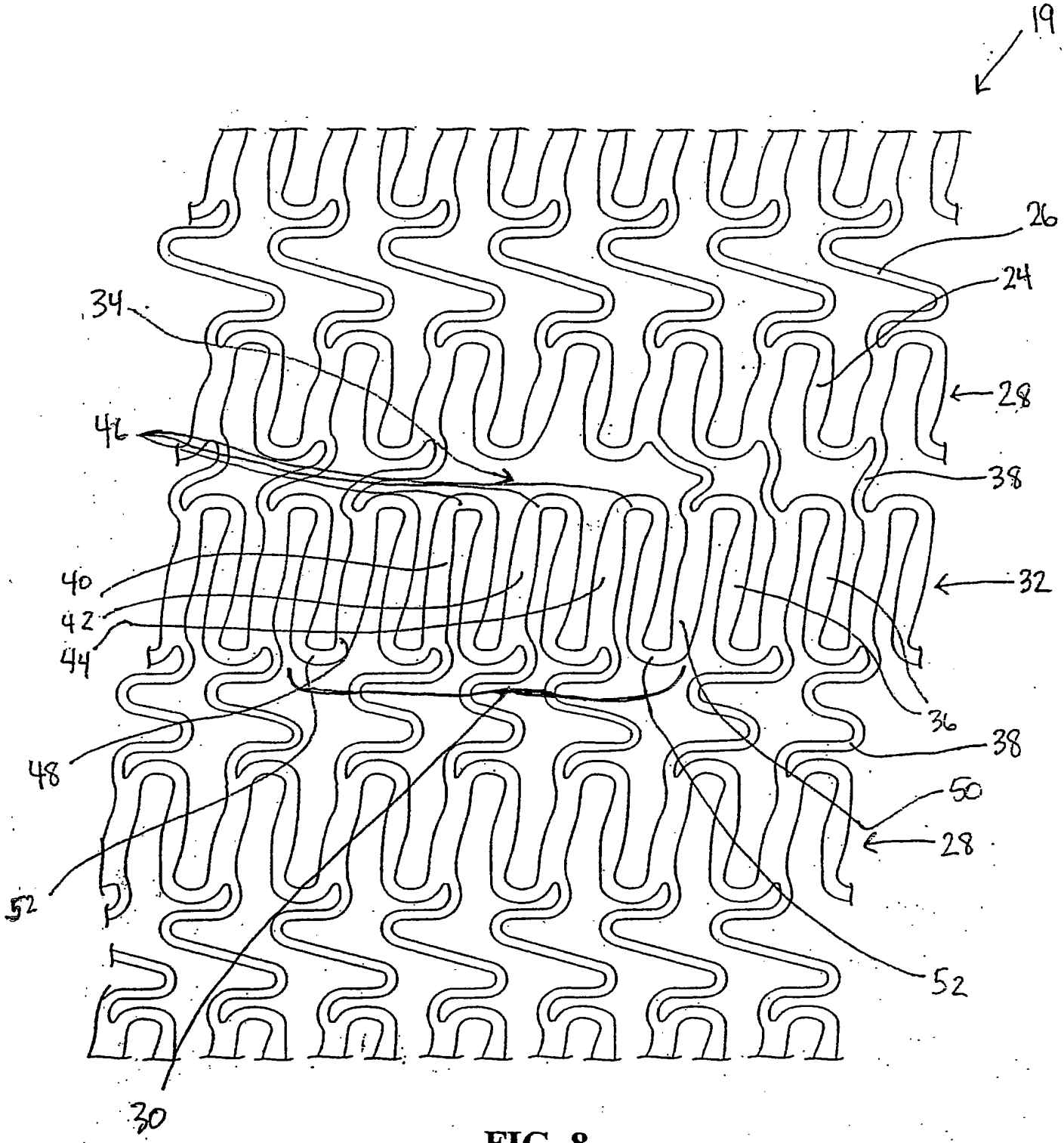


FIG. 8

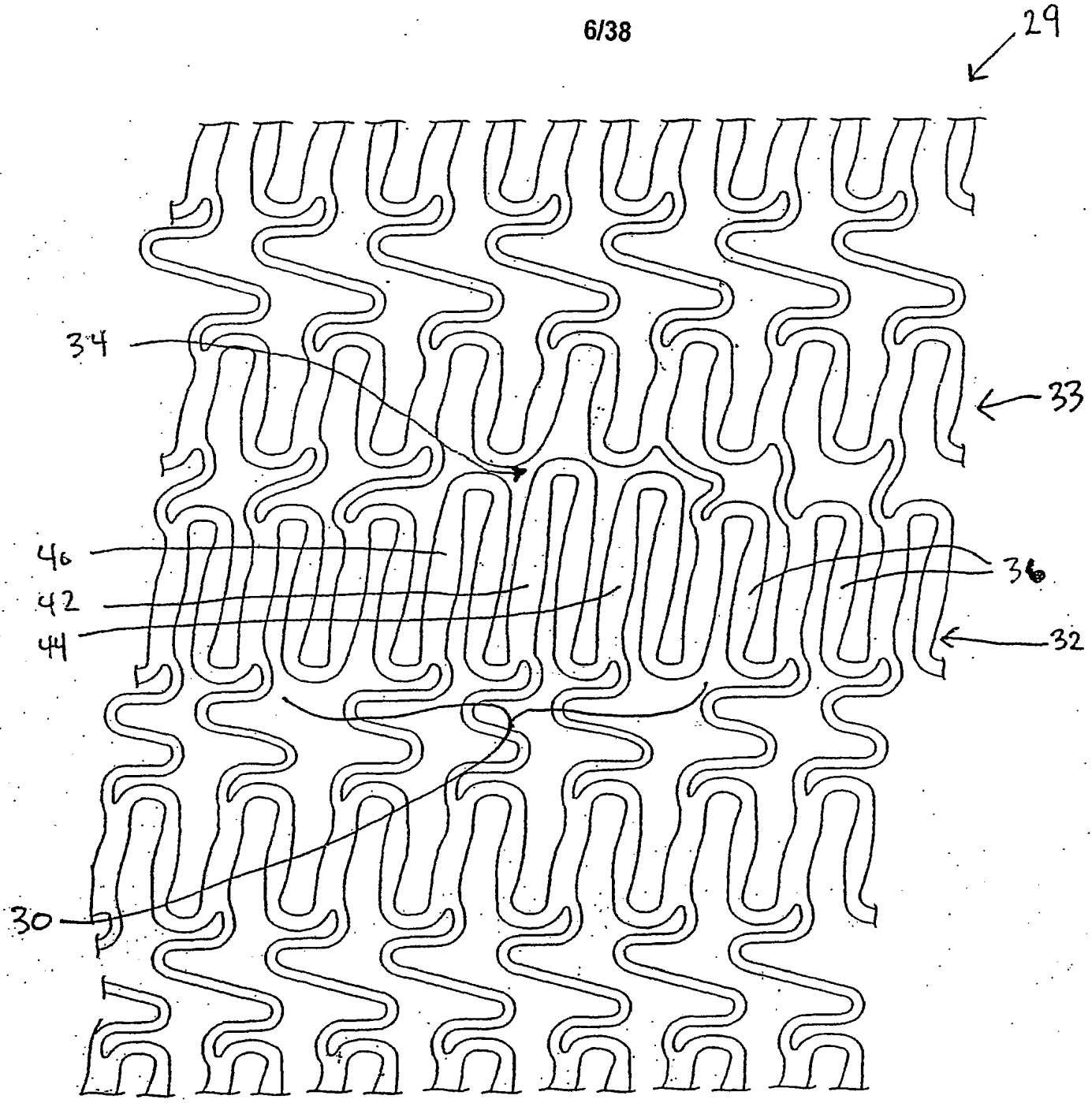


FIG. 9

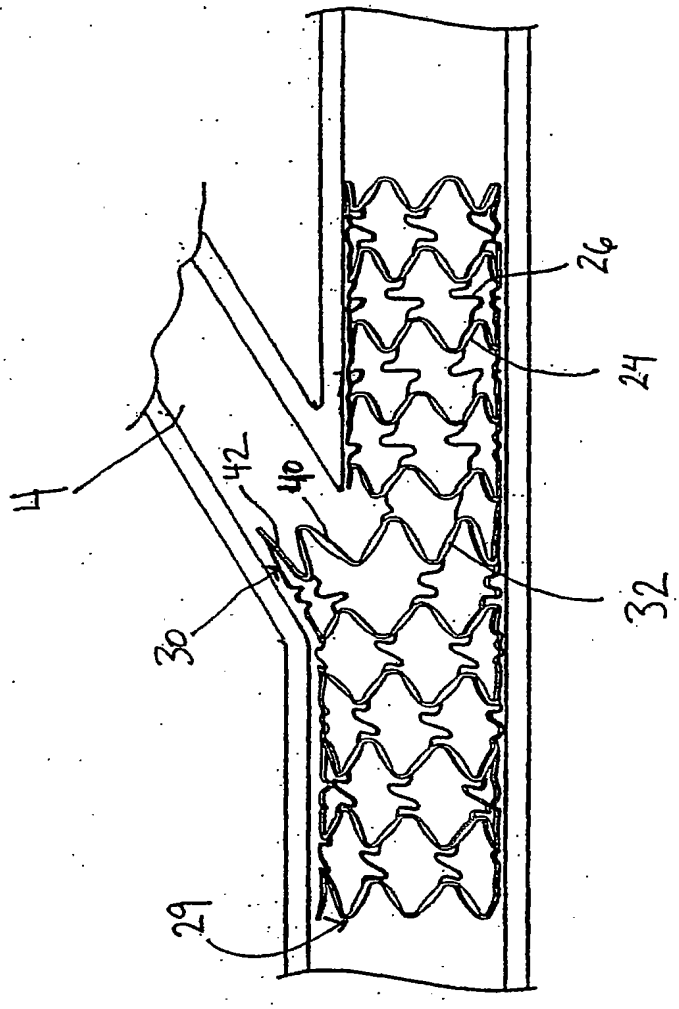


FIG. 10

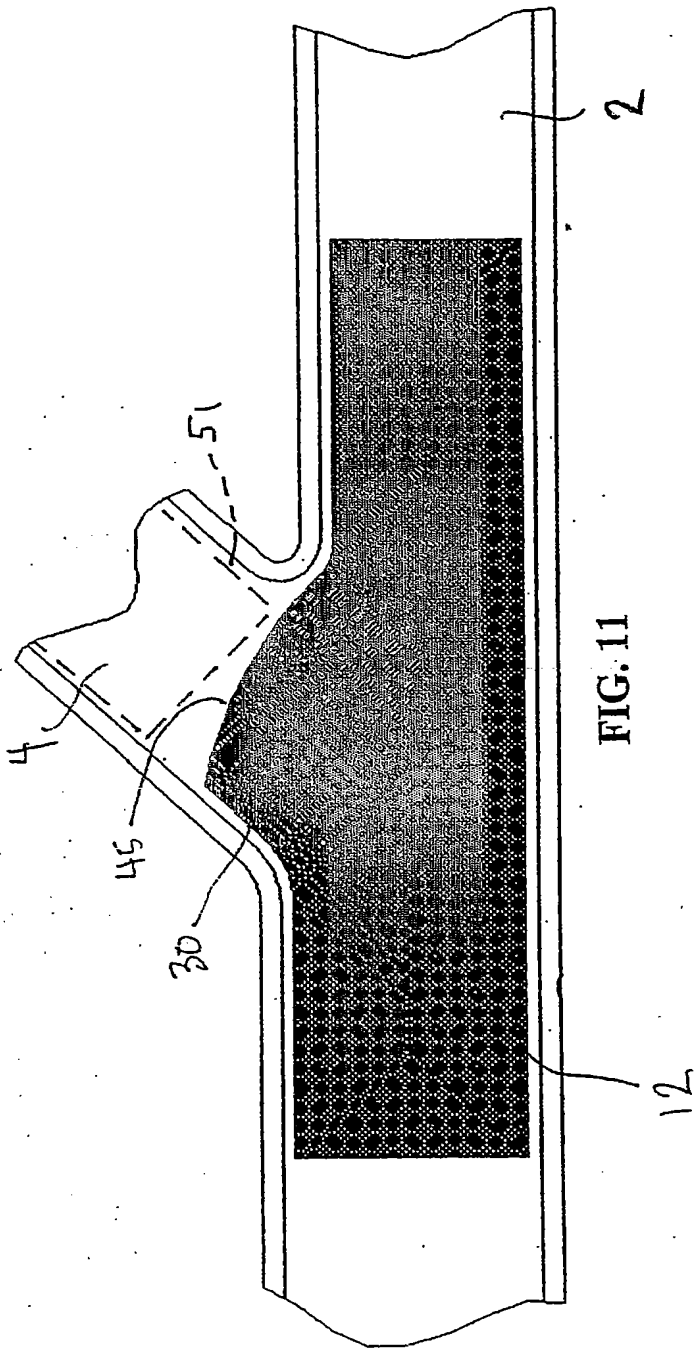


FIG. 11

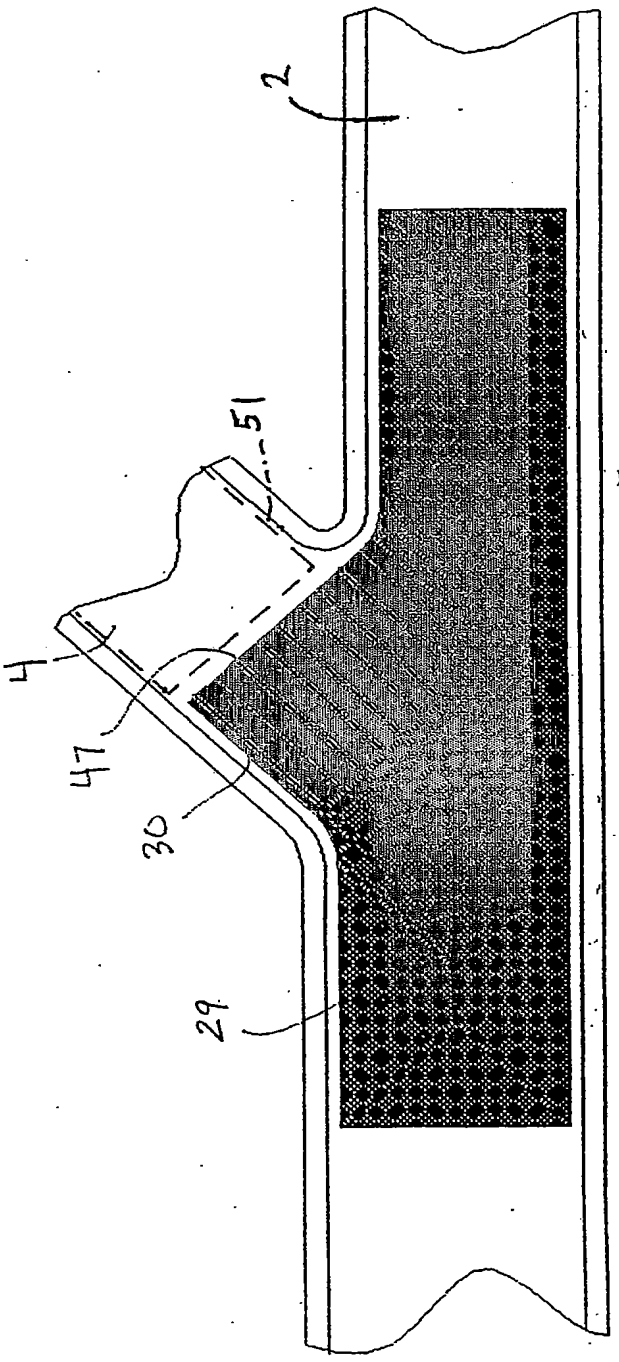


FIG. 12

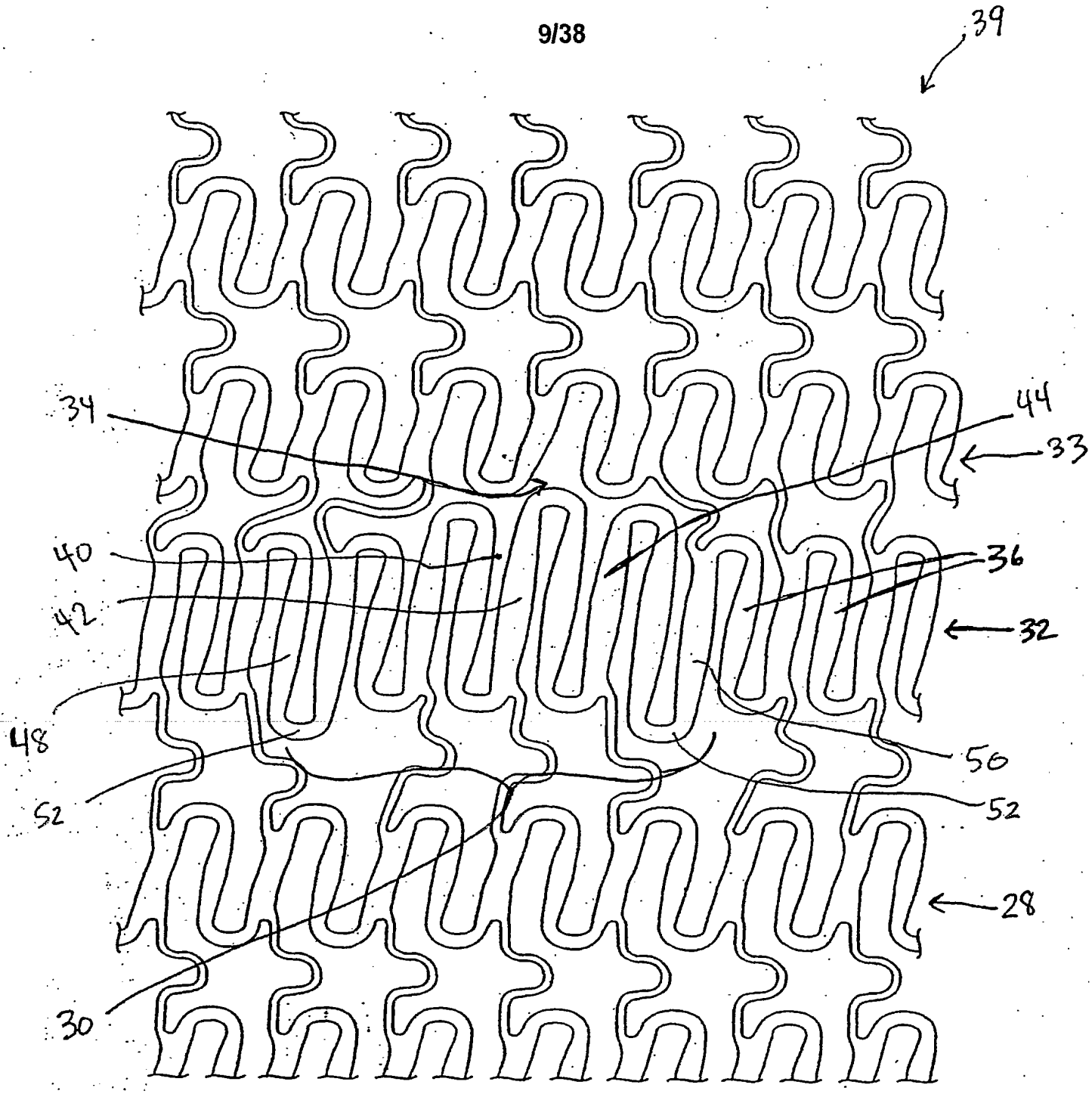


FIG. 13

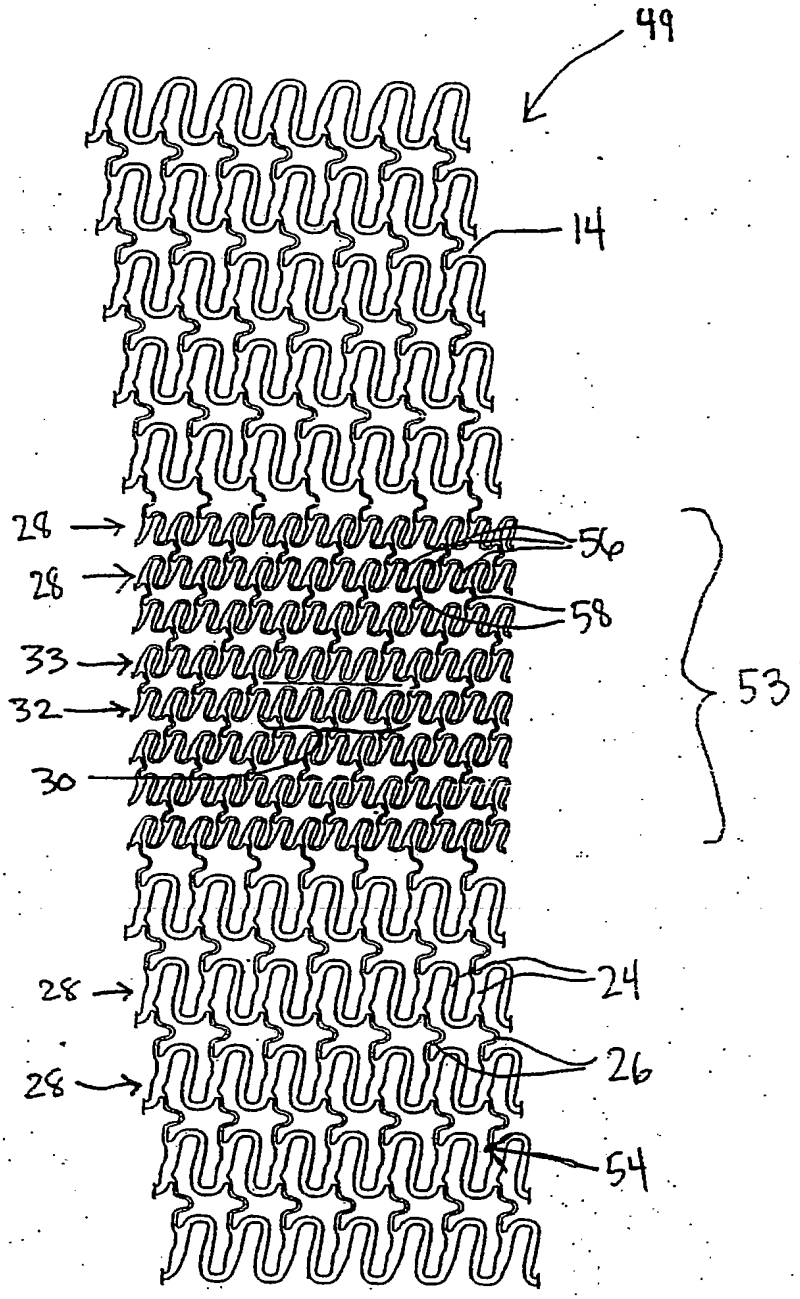


FIG. 14

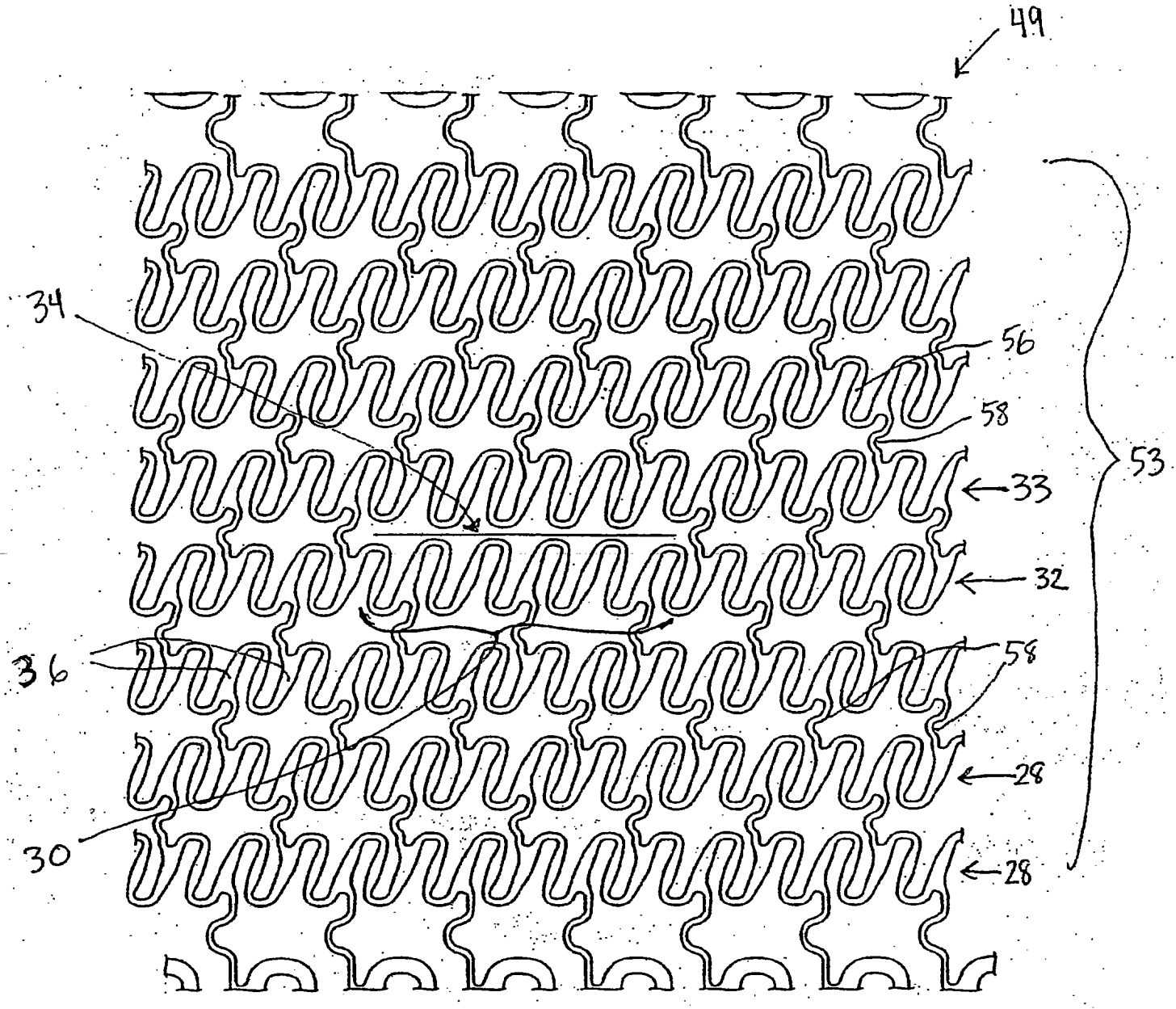


FIG. 15

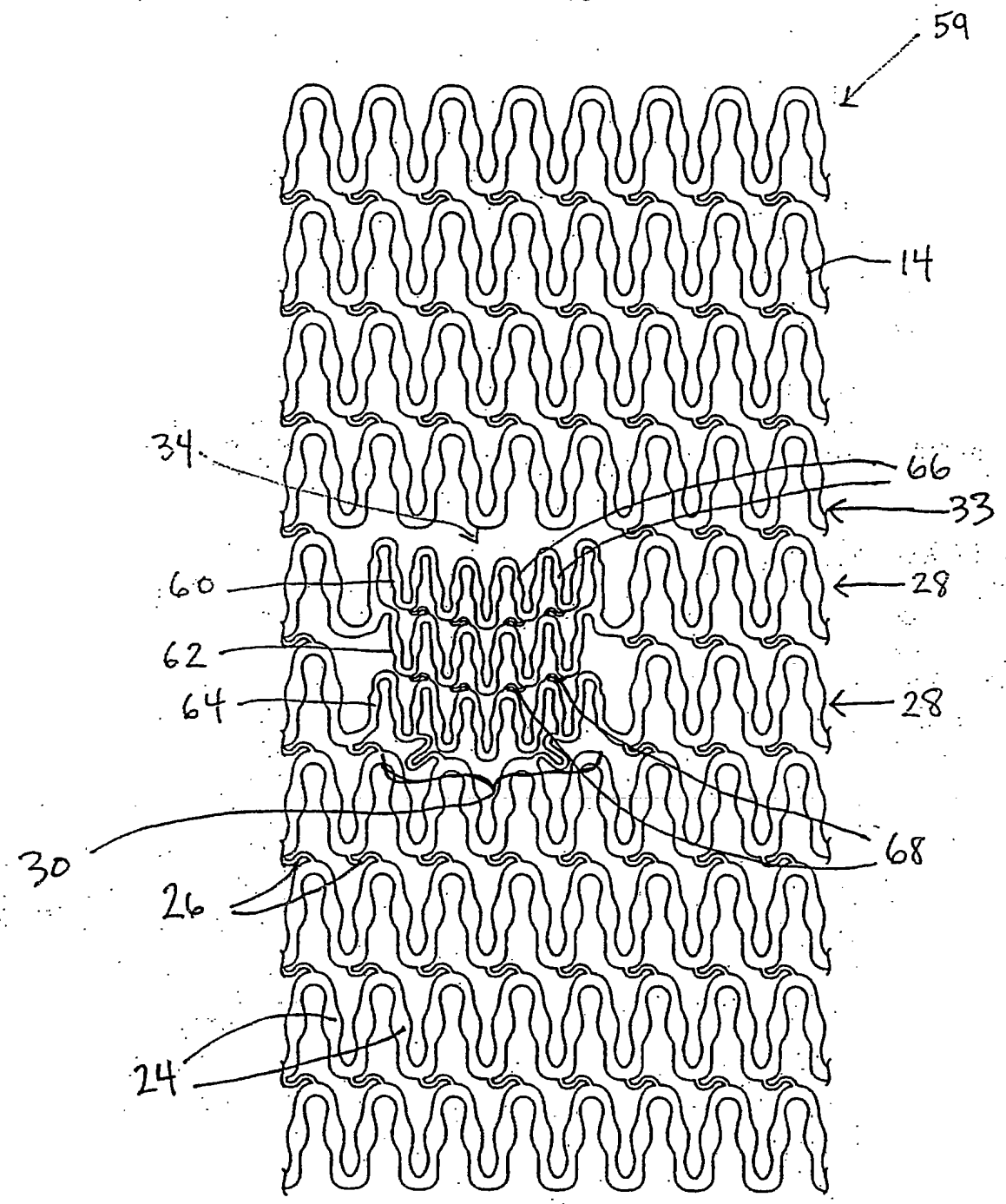


FIG. 16

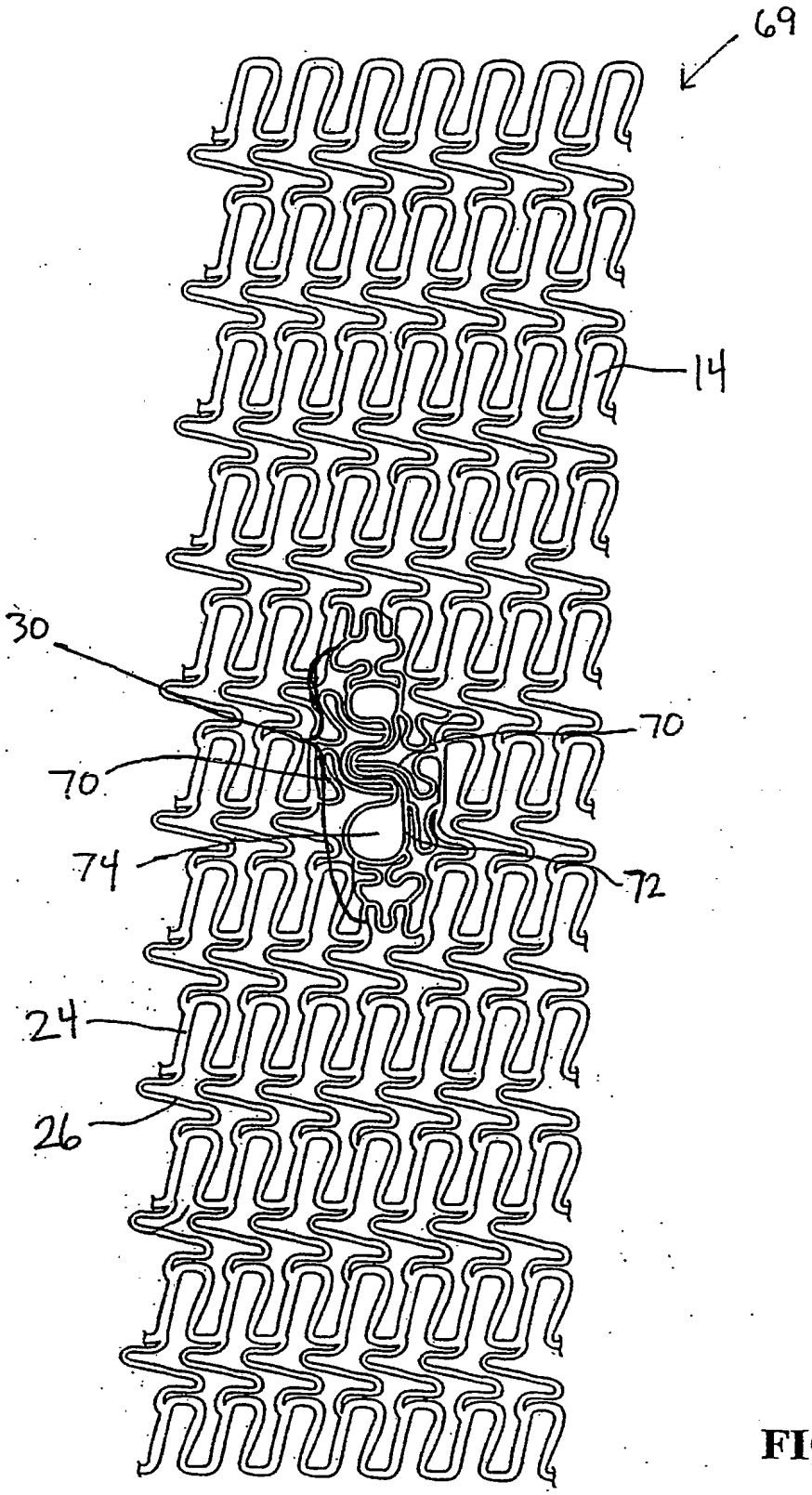


FIG. 17

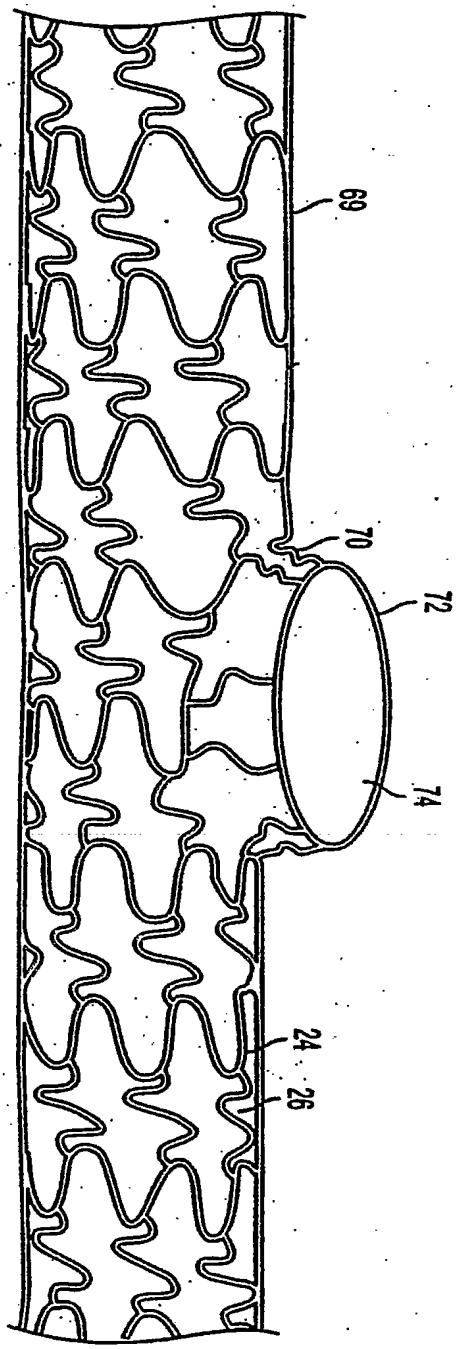


FIG. 18

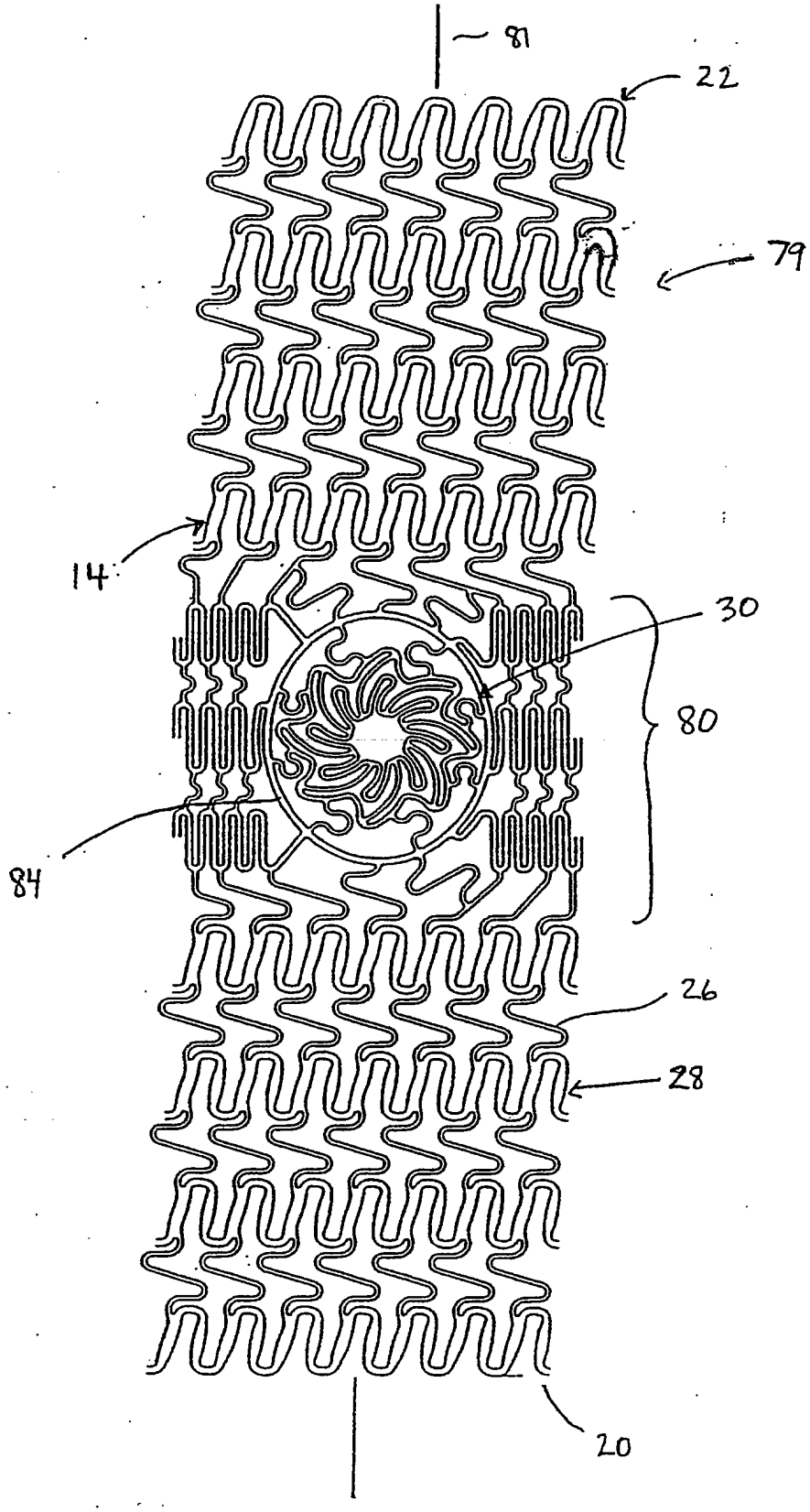


FIG. 19

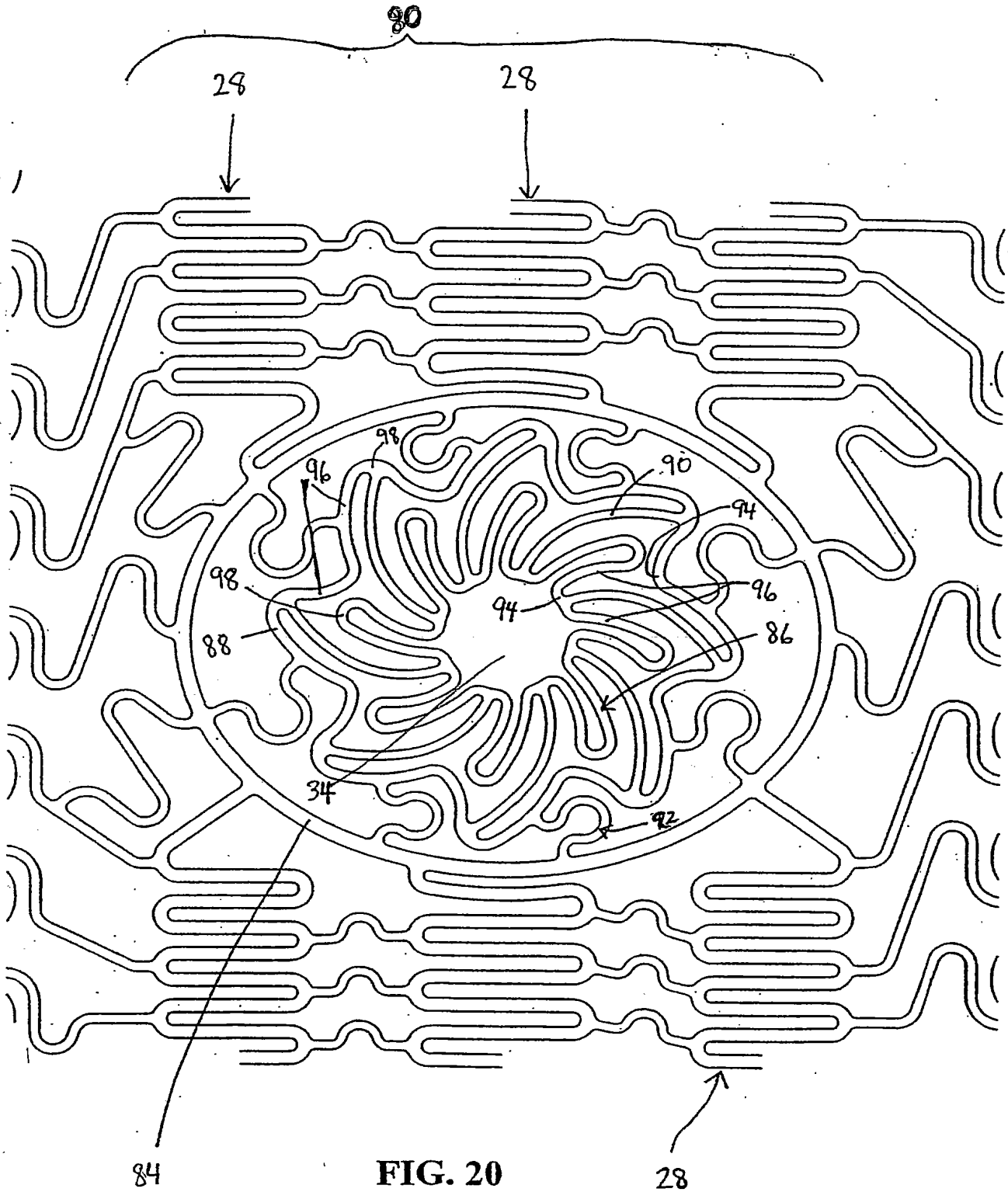


FIG. 20

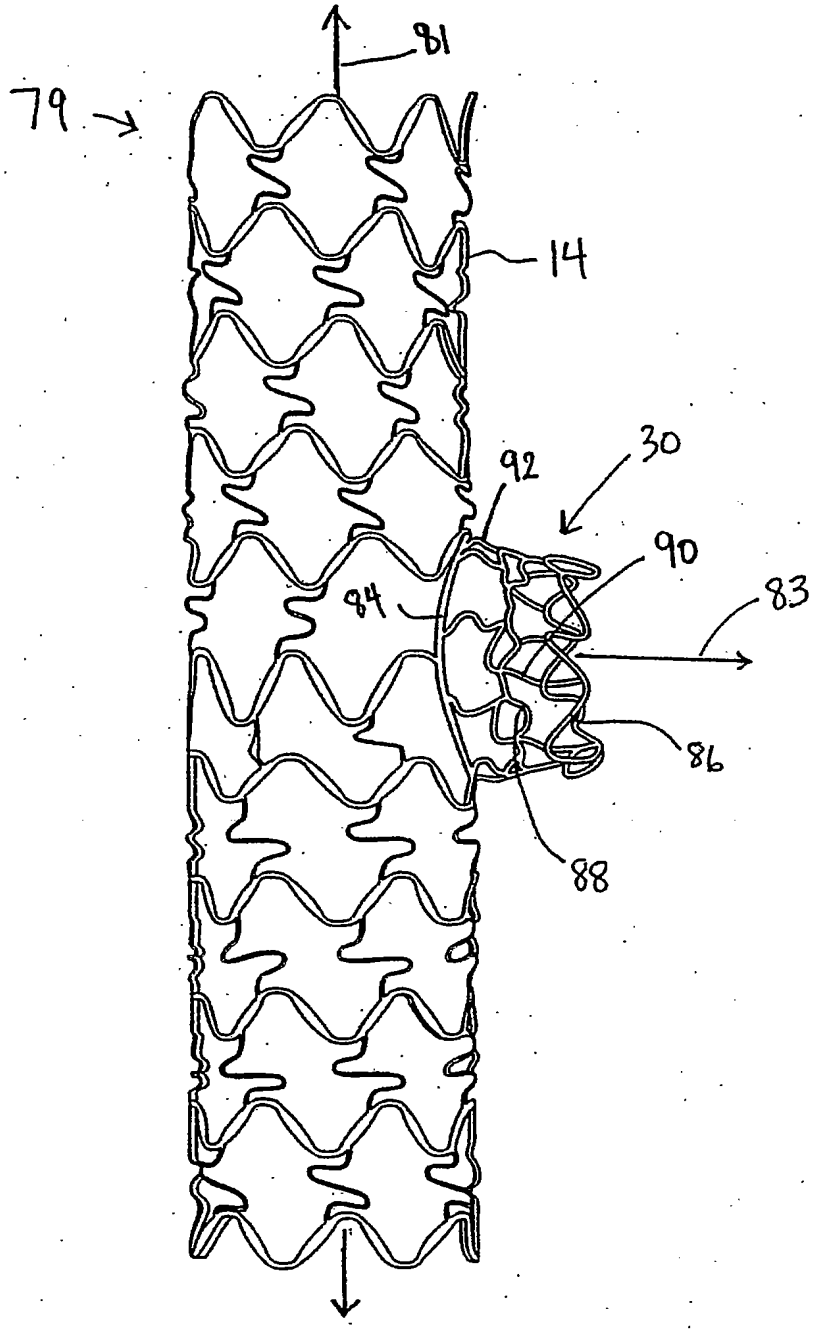
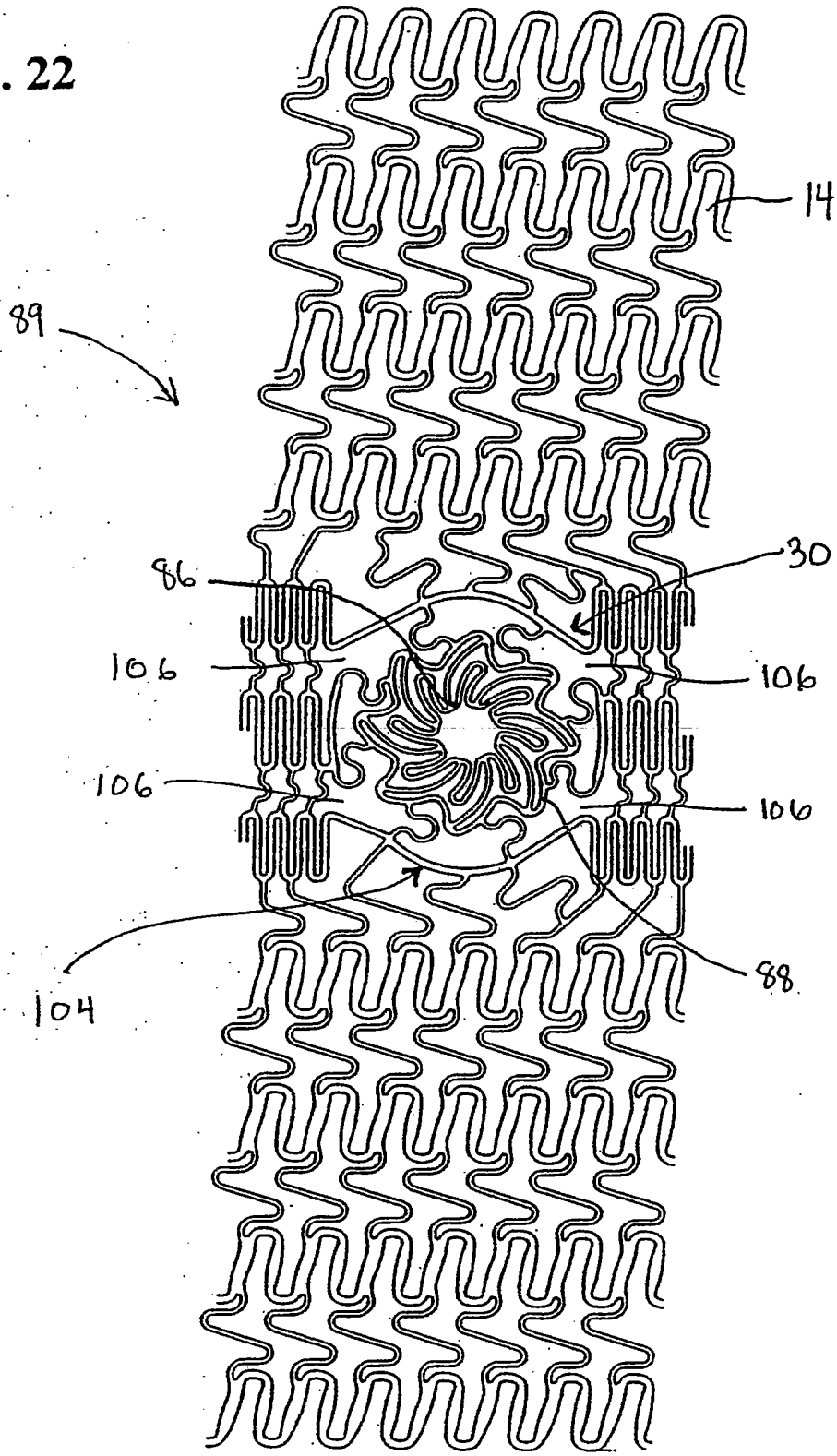


FIG. 21

FIG. 22



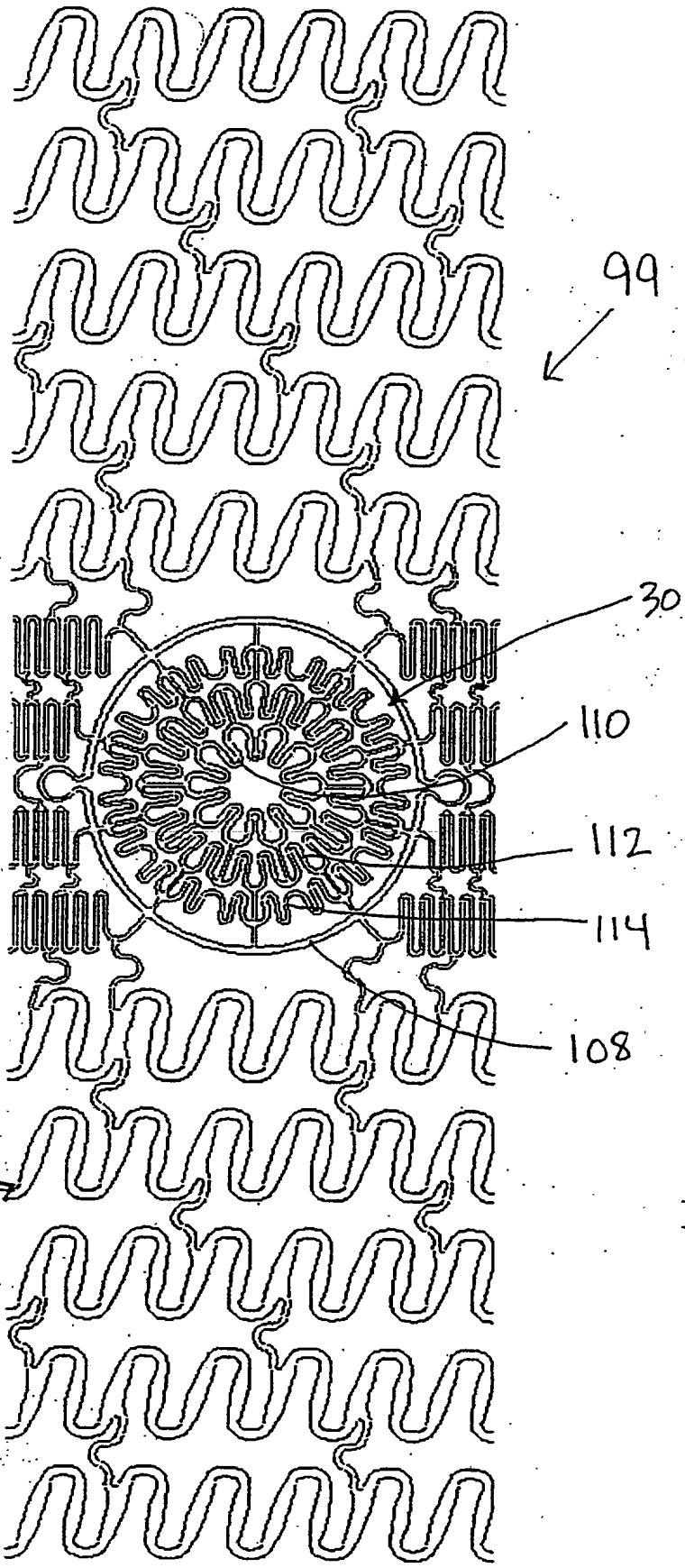


FIG. 23

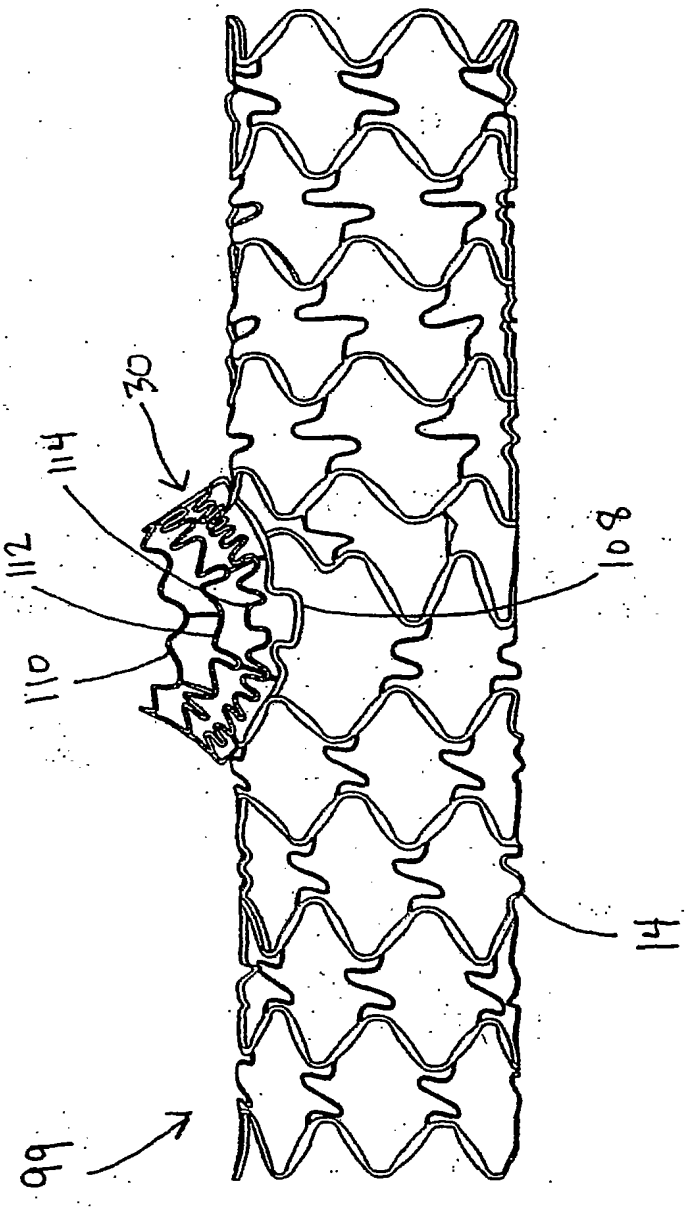


FIG. 24

FIG. 25

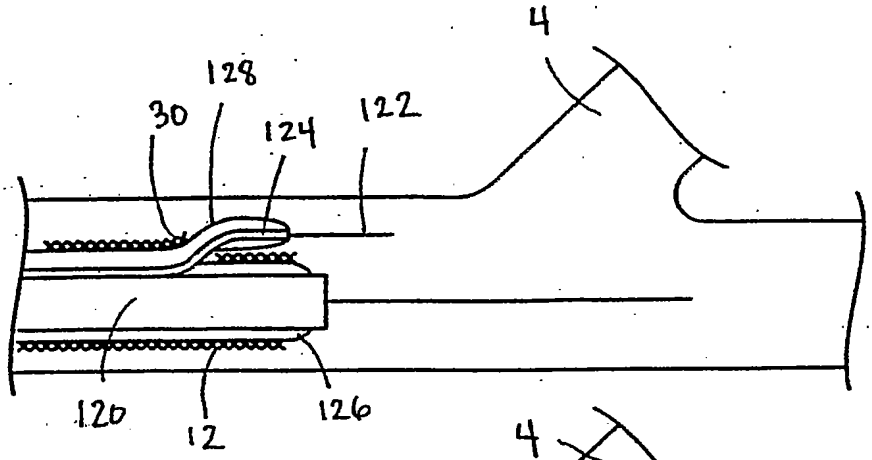


FIG. 26

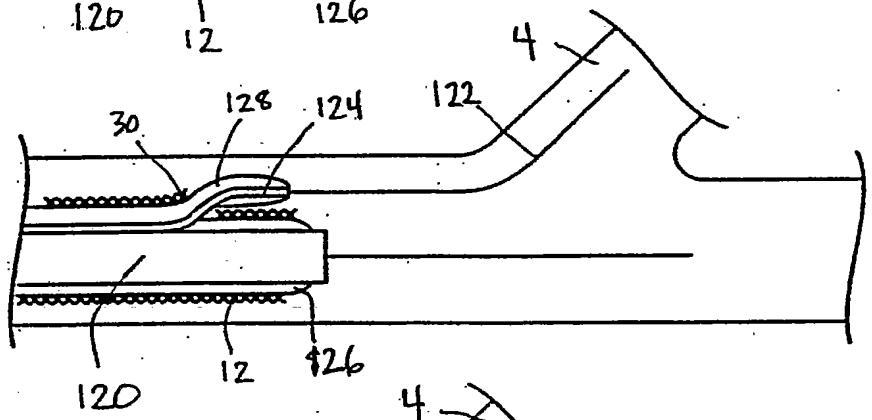


FIG. 27

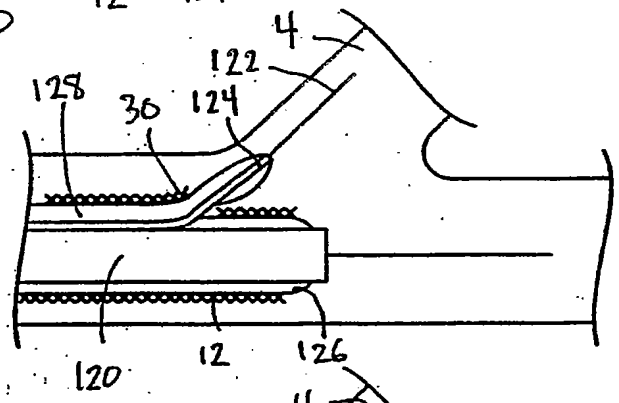


FIG. 28

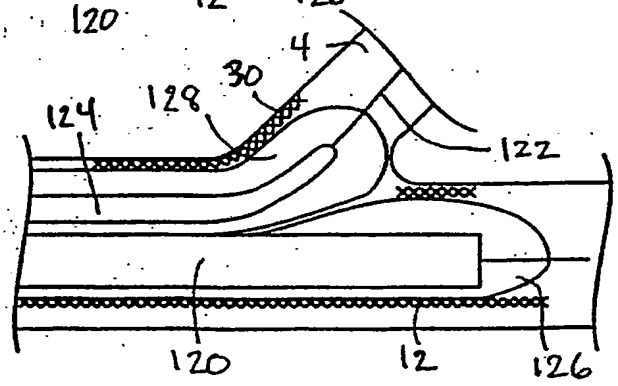


FIG. 29

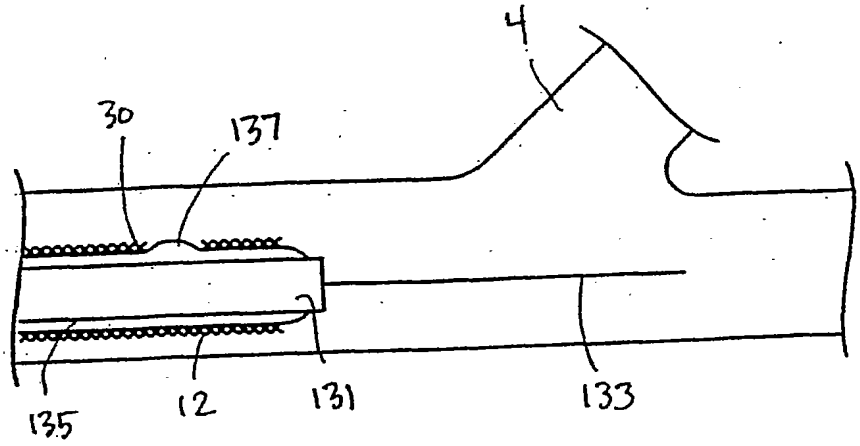


FIG. 30

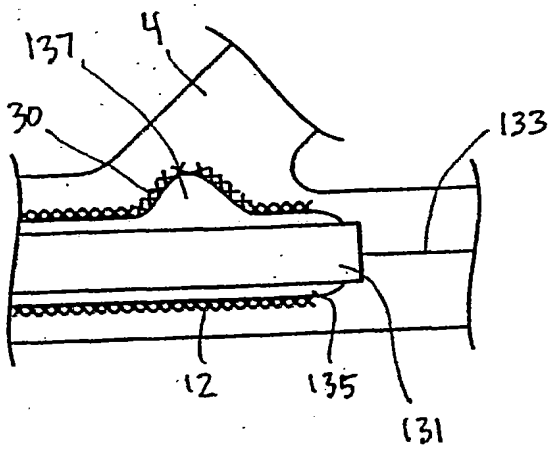
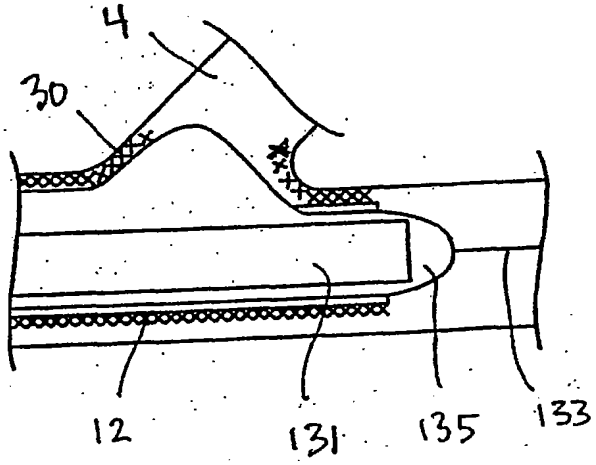


FIG. 31



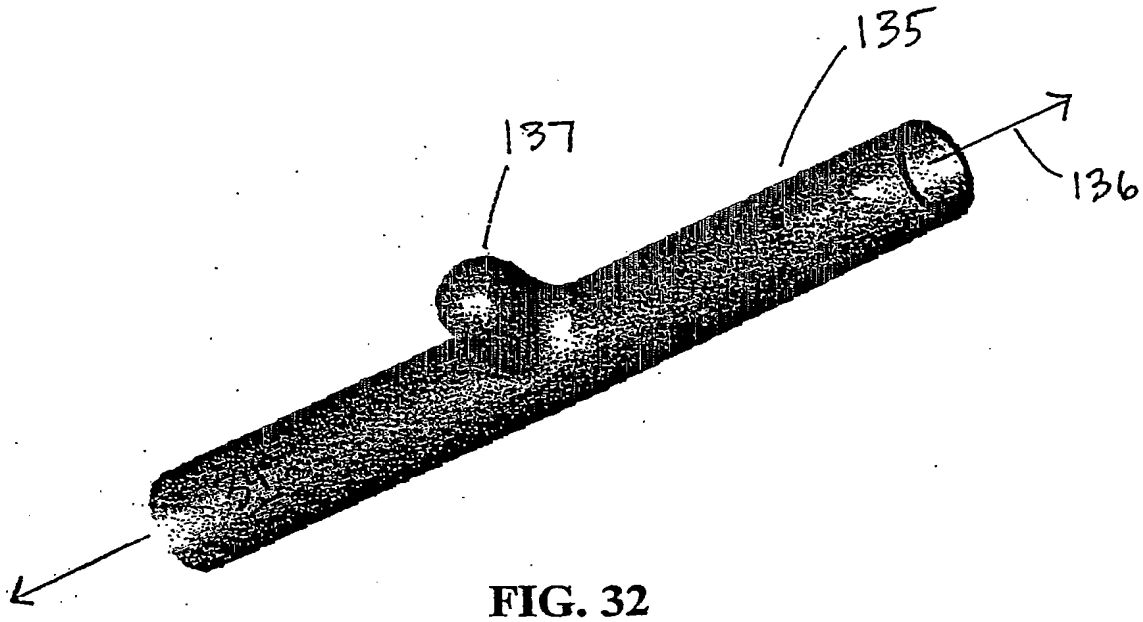


FIG. 32

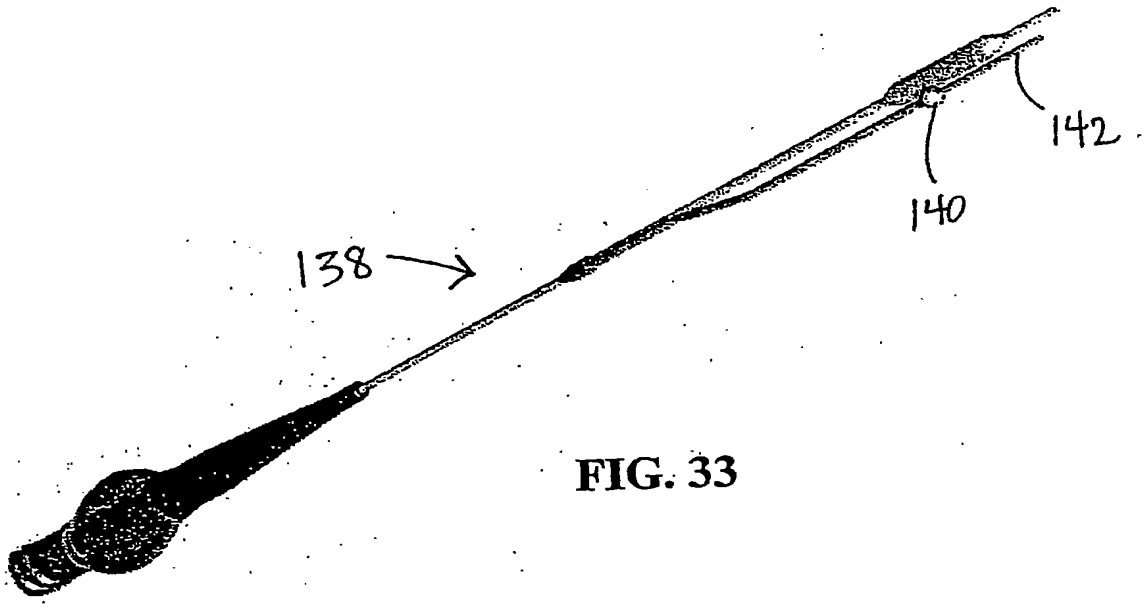


FIG. 33

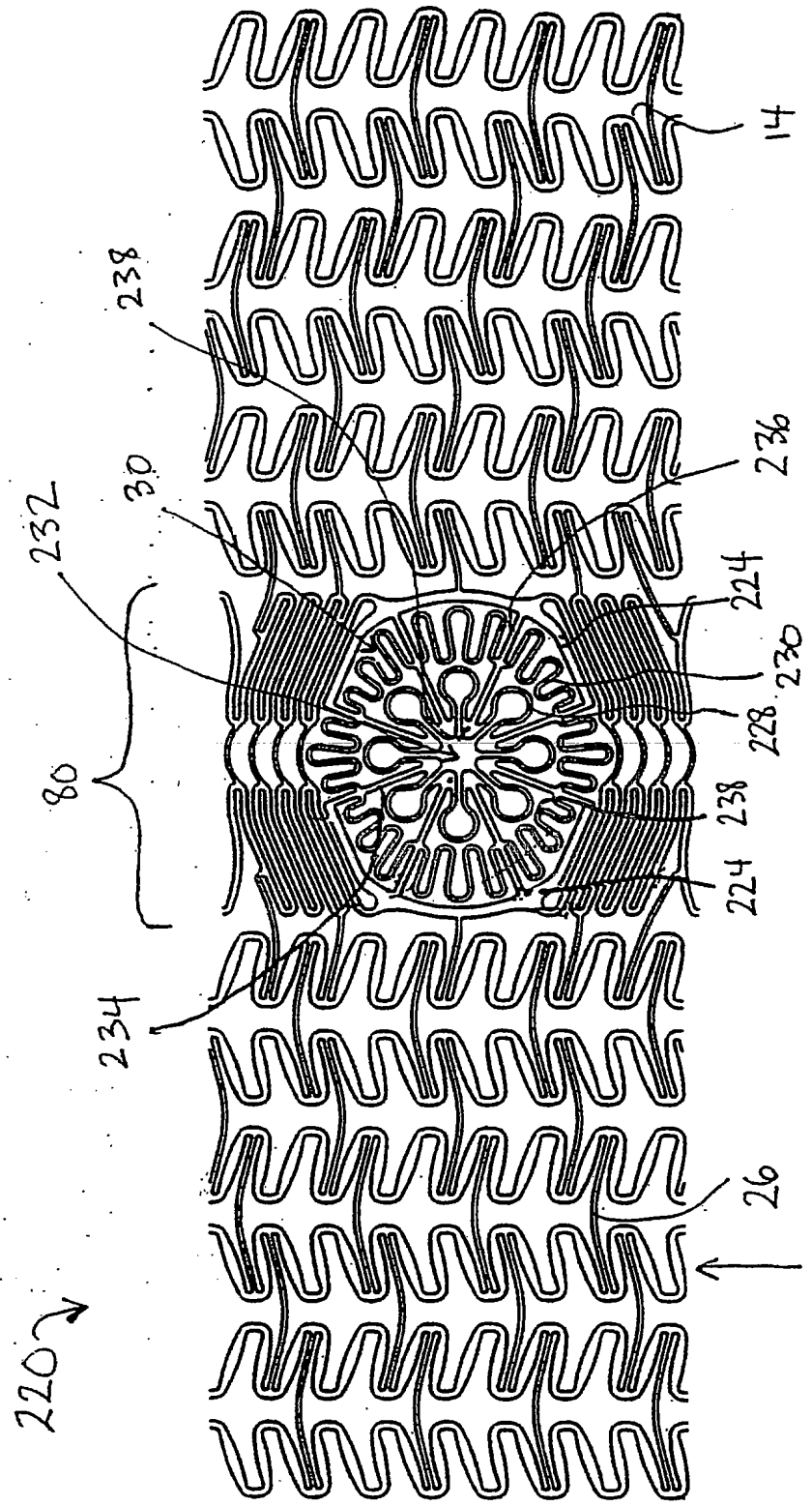


FIG. 34

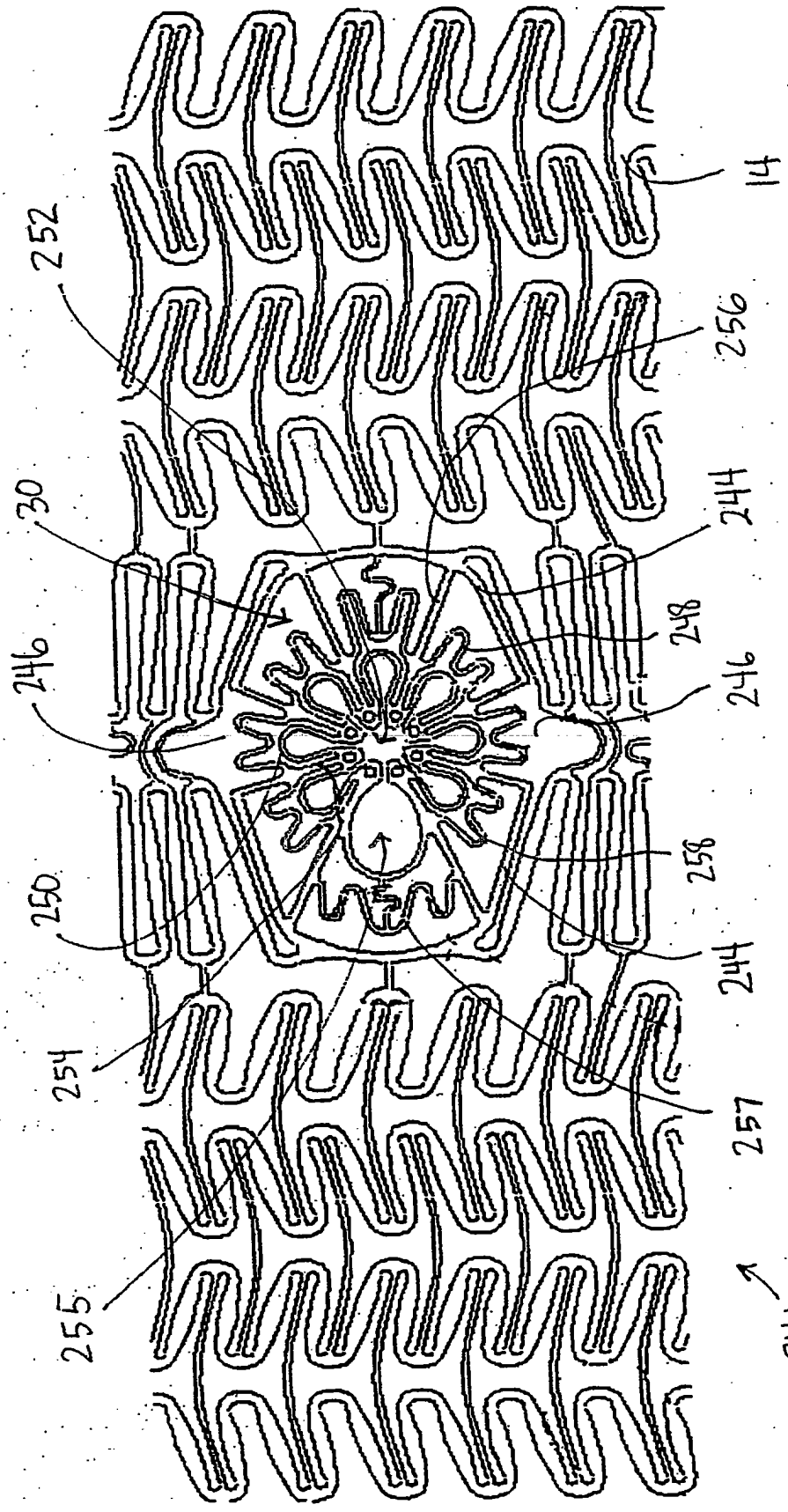


FIG. 35

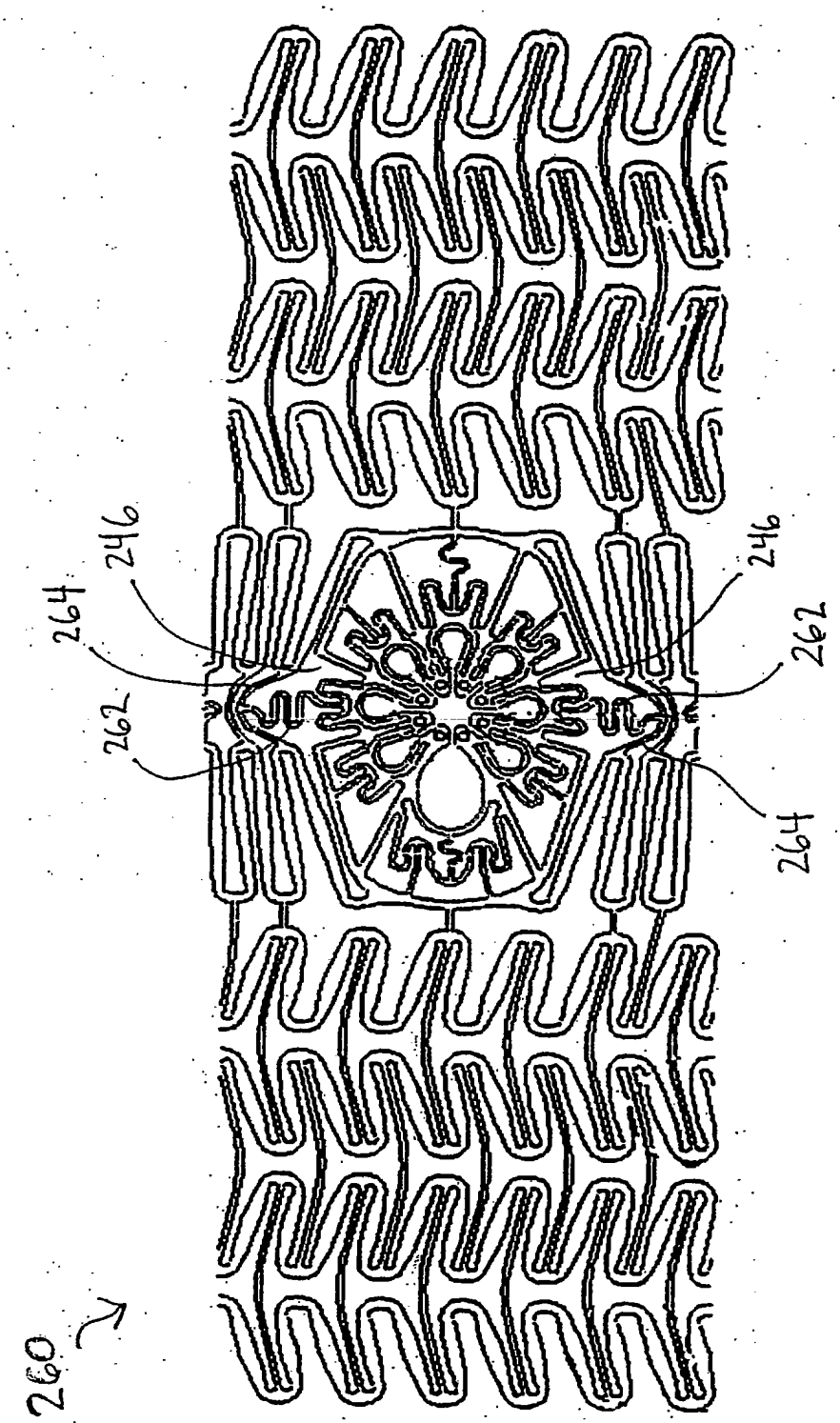


FIG. 36

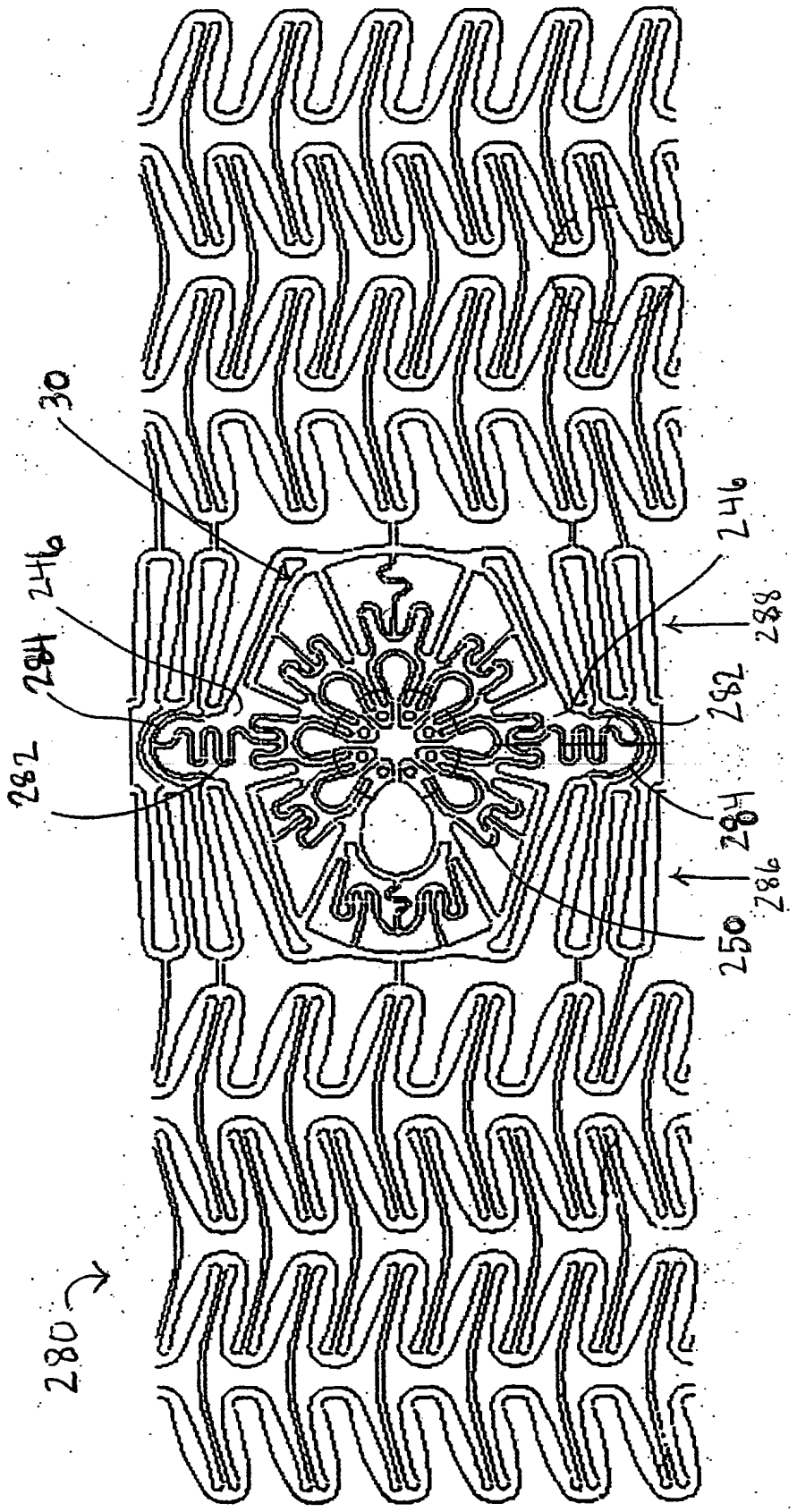


FIG. 37

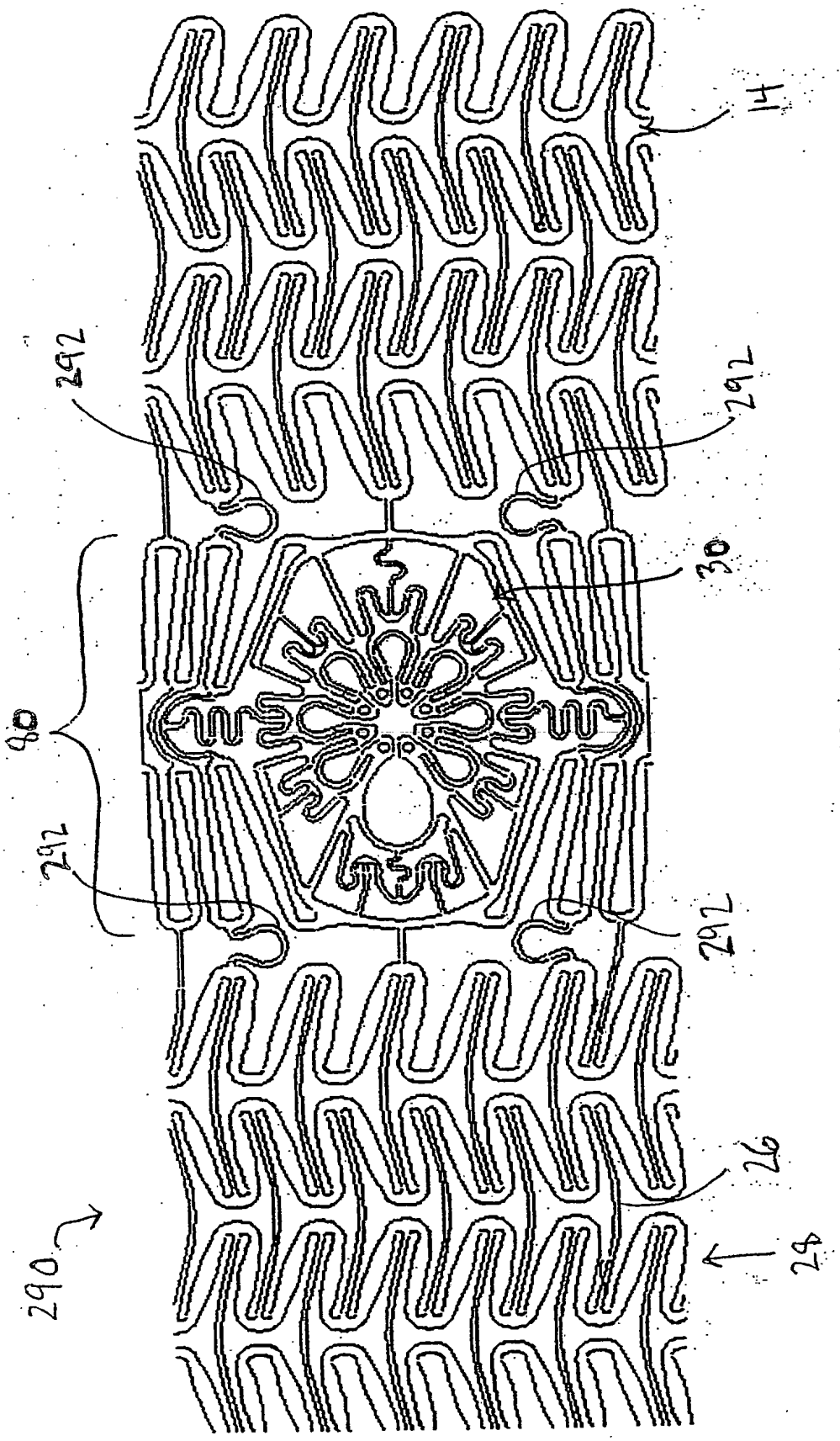


FIG. 38

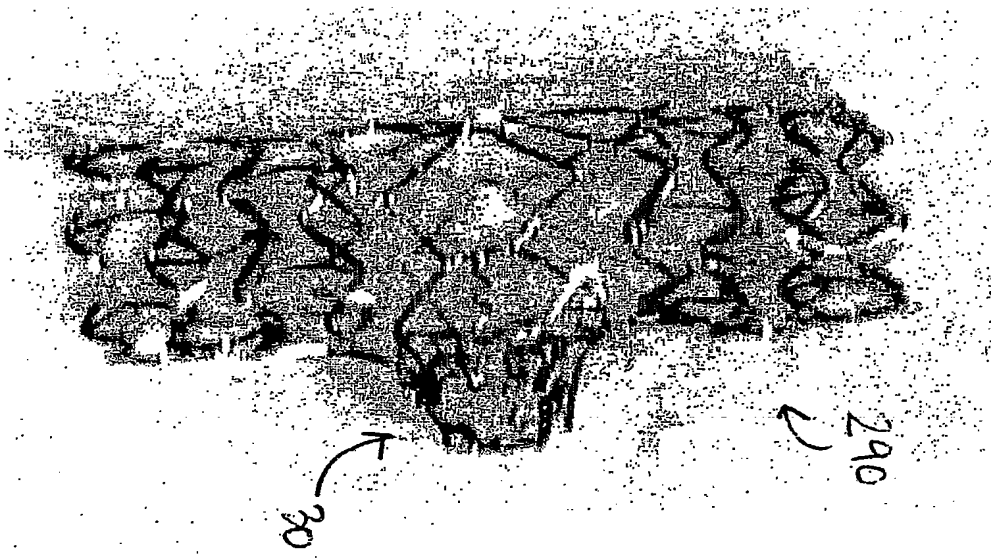


FIG. 39

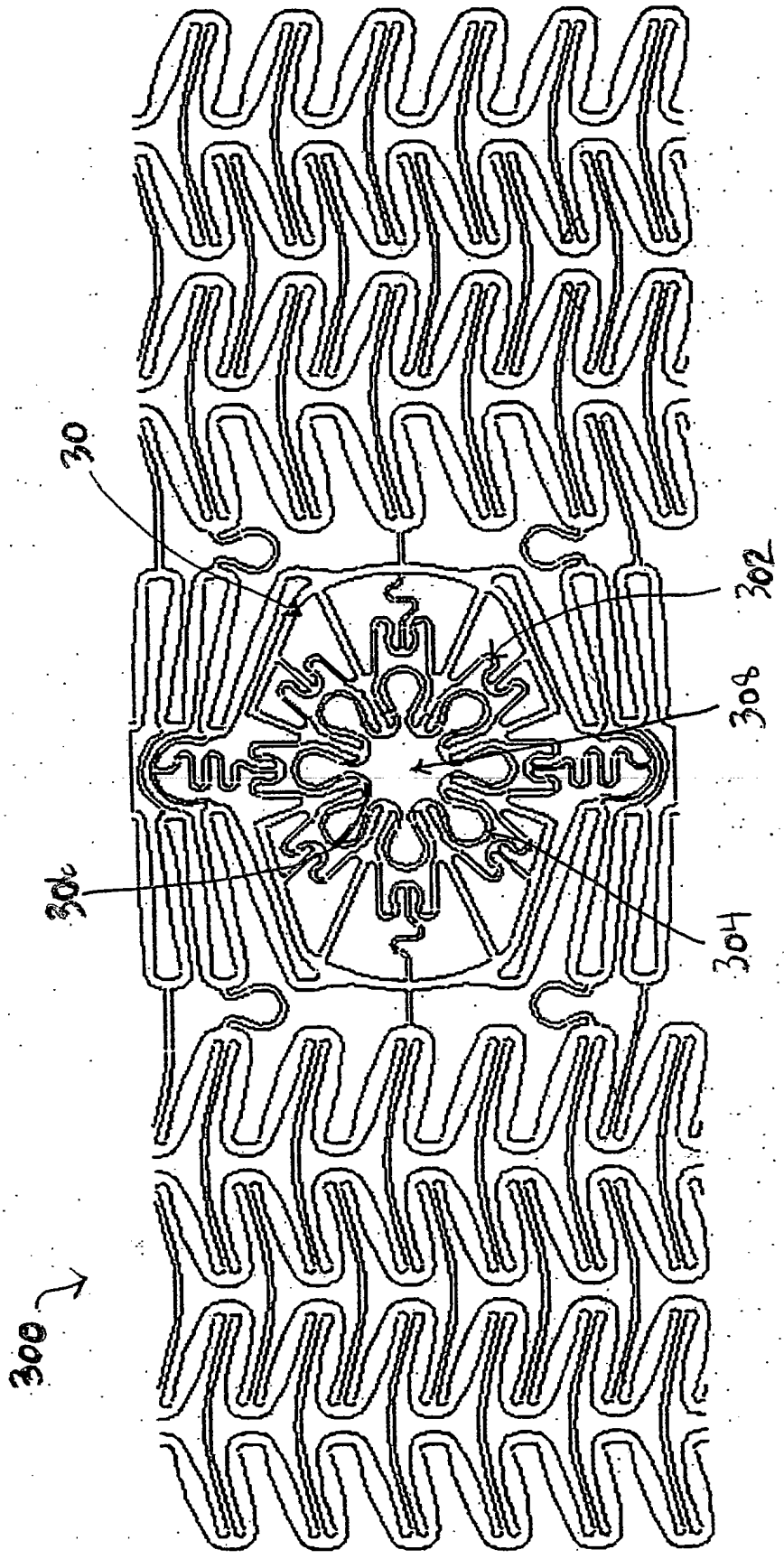


FIG. 40

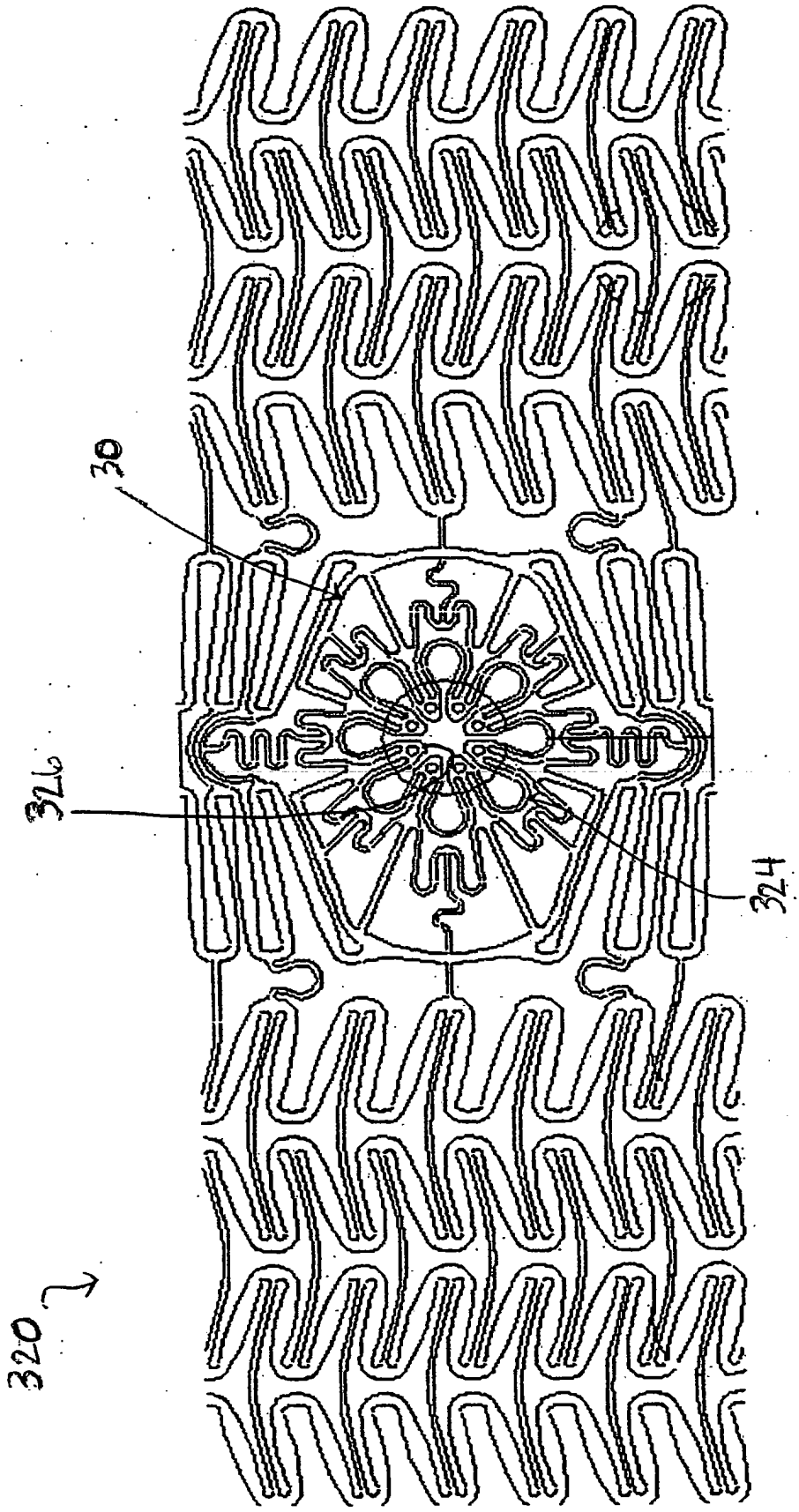


FIG. 41

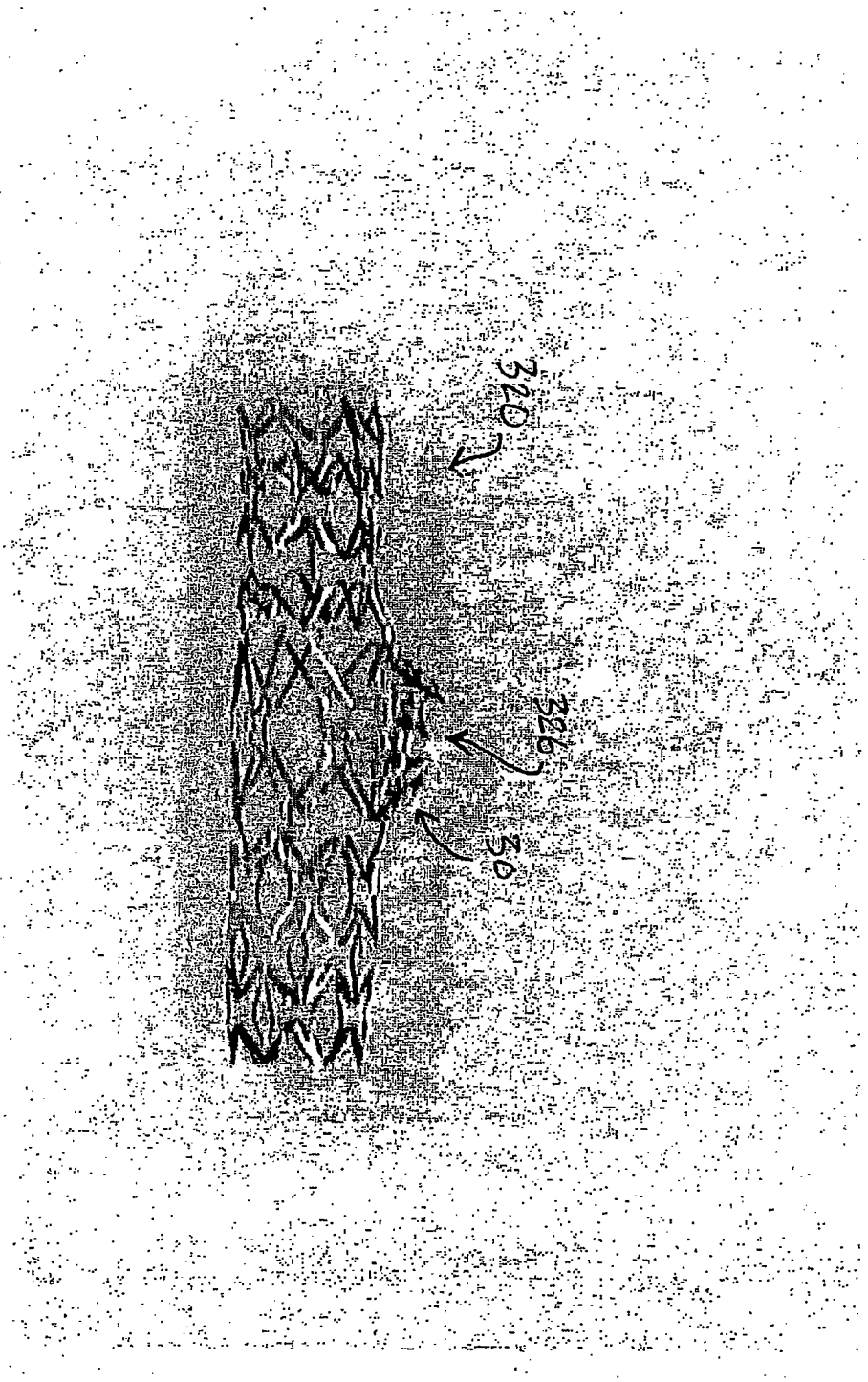


FIG. 42

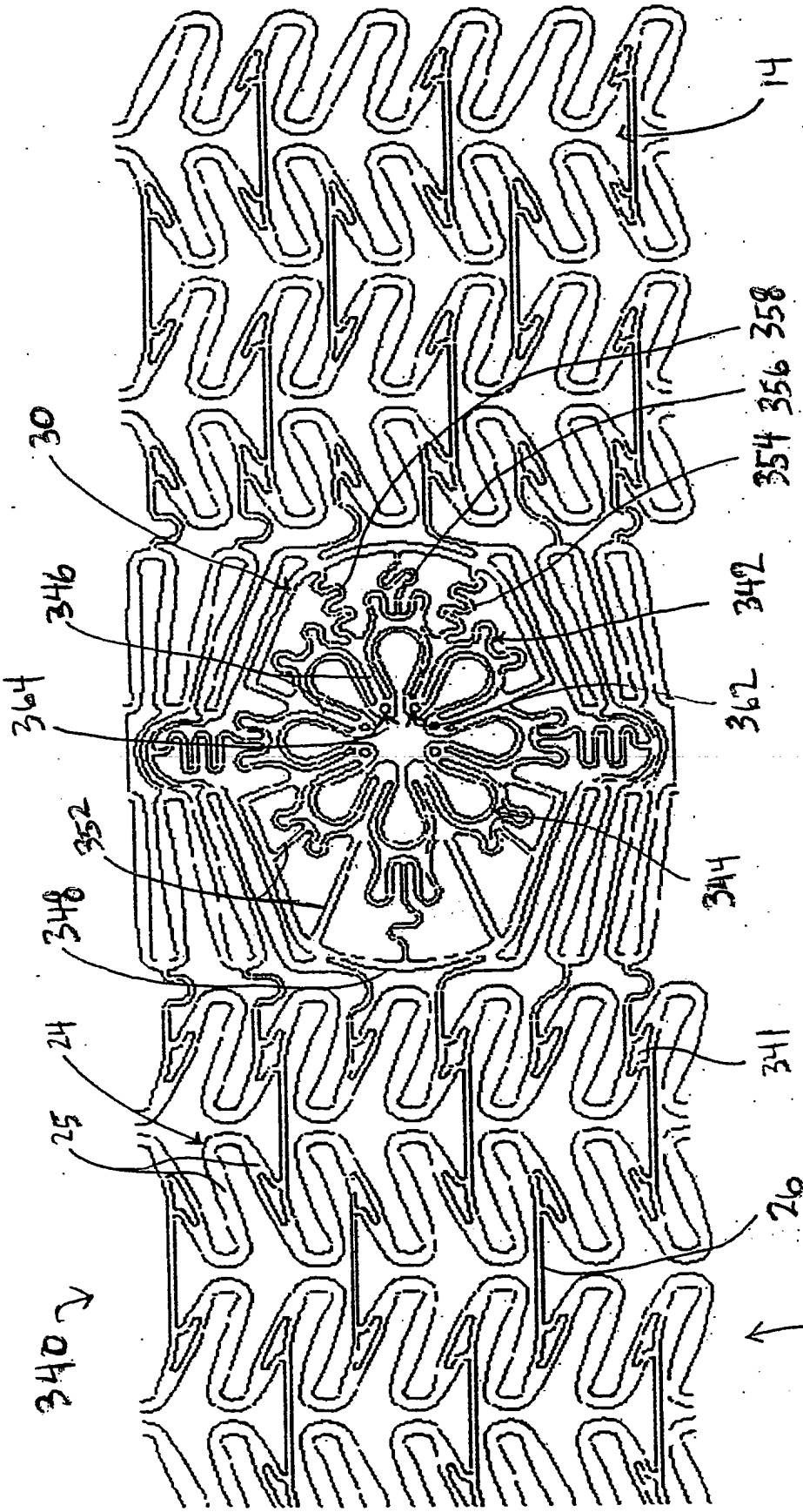


FIG. 43

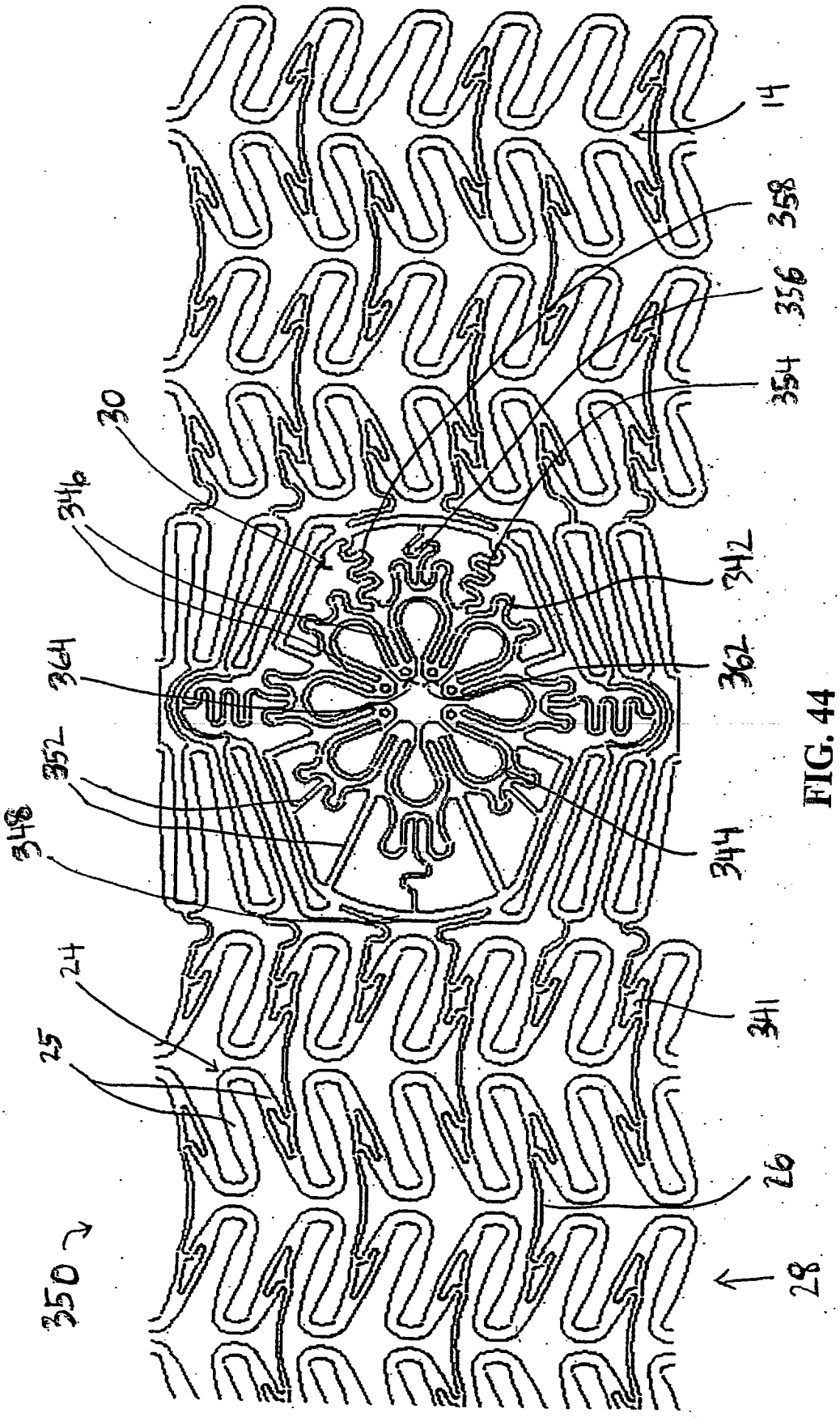


FIG. 44

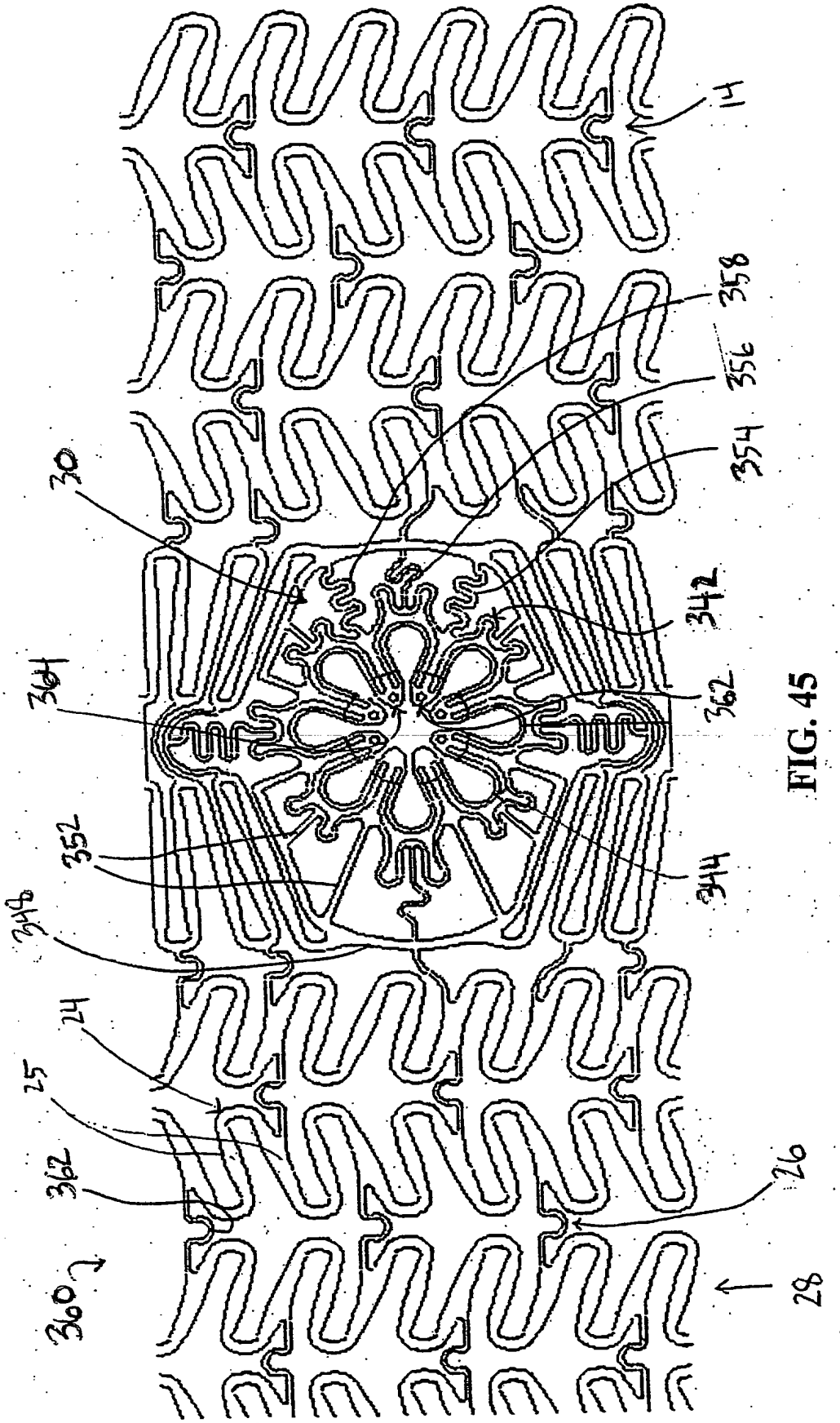


FIG. 45

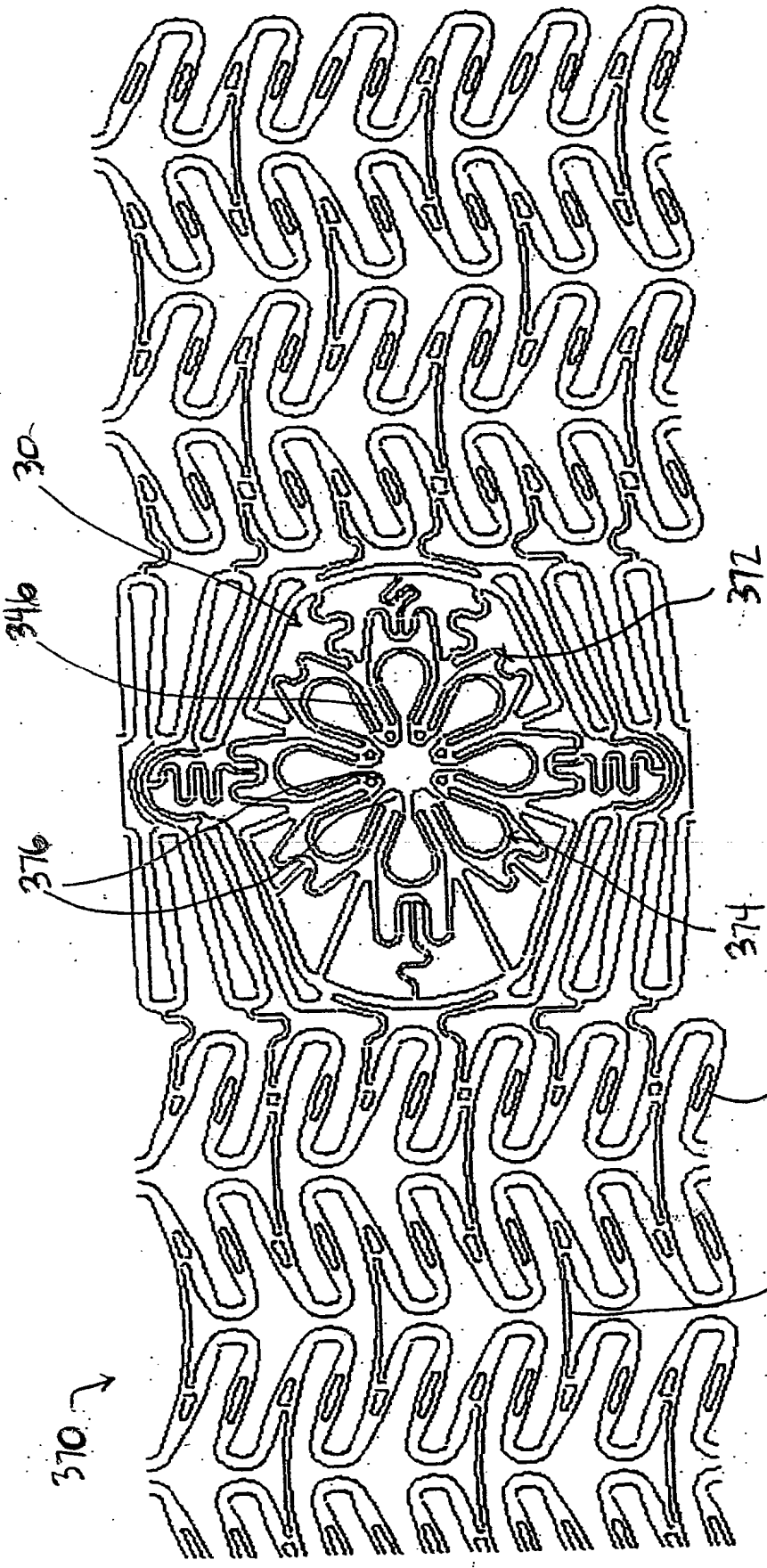


FIG. 46

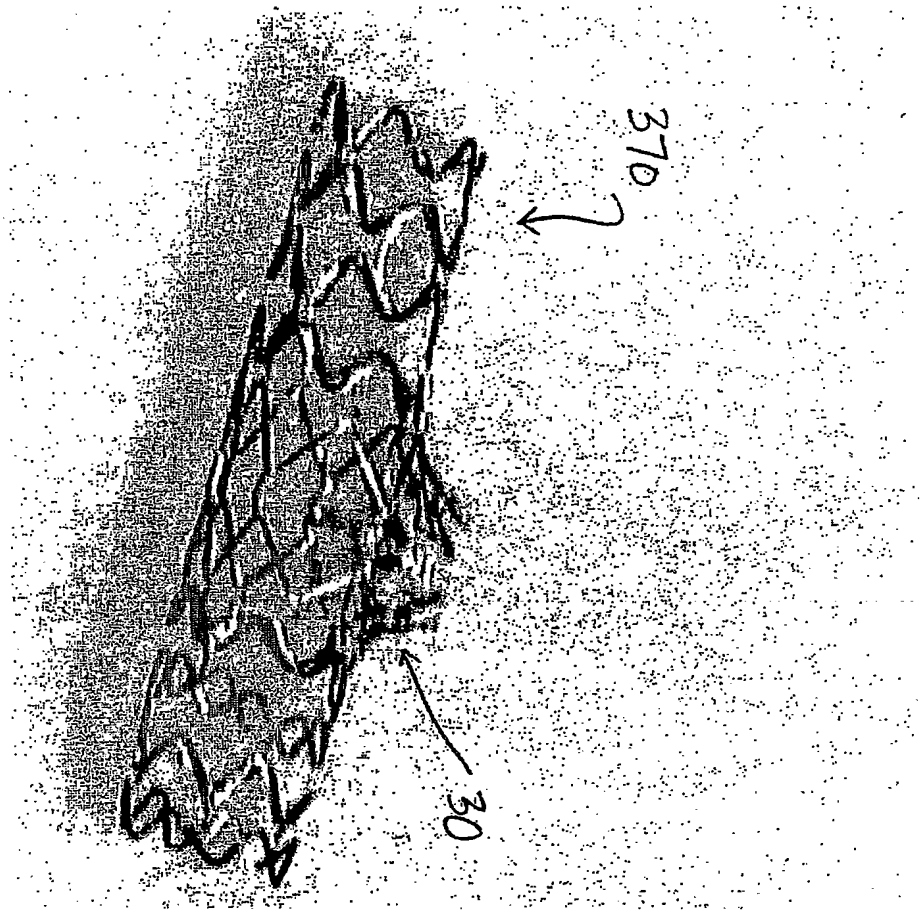


FIG. 47

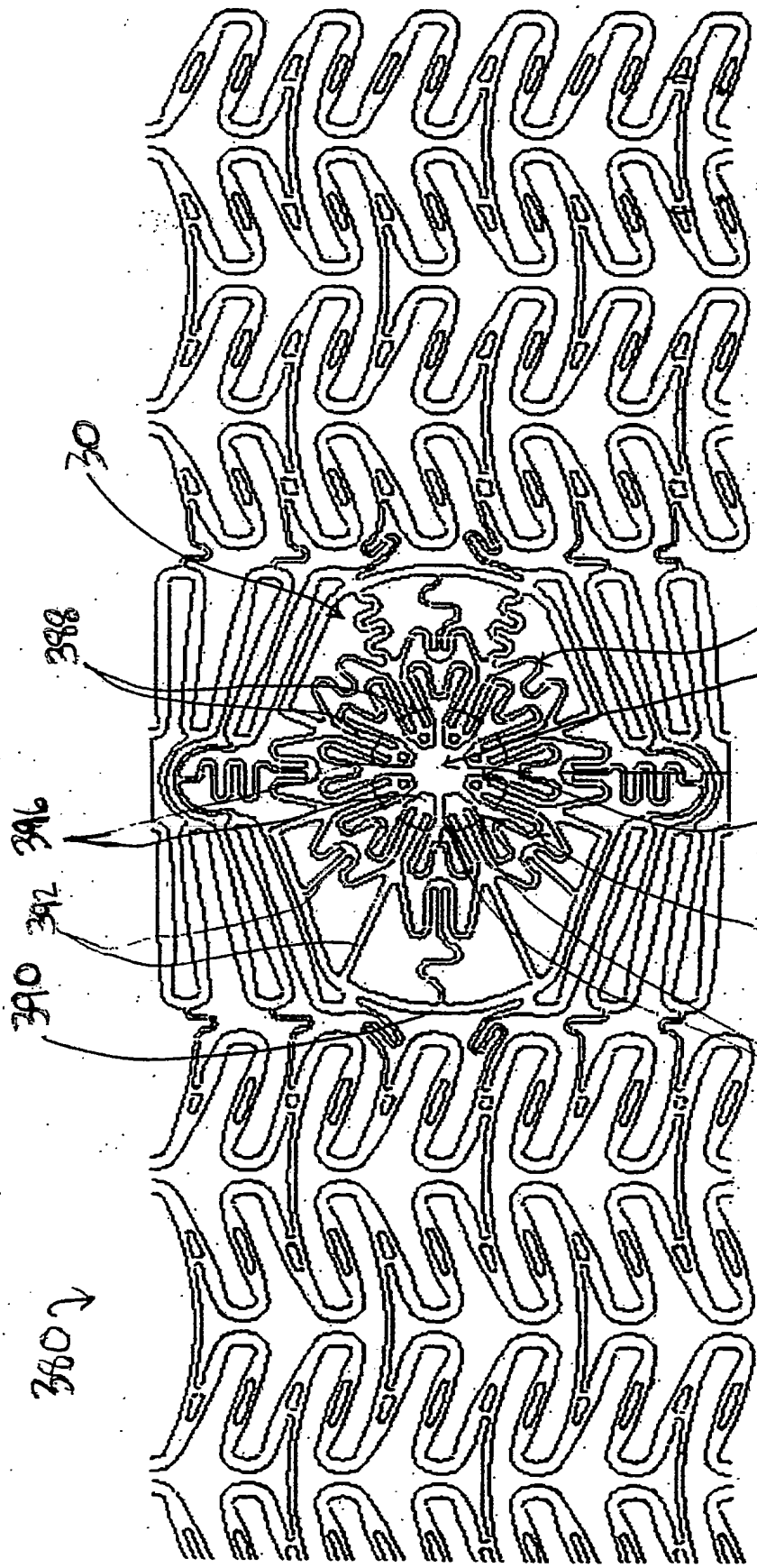


FIG. 48

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/22206

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61F 2/06
US CL : 623/1.35
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1.35, 1.1, 1.15, 1.16, 1.21 1.32, 12, 11.11, 66.1; 606/191, 194; 128/898

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,325,826 B1 (VARDI et al) 04 December 2001 (04.12.2001), see Figures 7-11 and column 8, lines 13-57.	1-20
A	US 2002/0193873 A1 (BRUCKER et al) 19 December 2002 (19.12.2002), see Figures 1, 2 and 7 and paragraph [0062].	1-20
A, P	US 2004/0117003 A1 (OURIEL et al) 17 June 2004 (17.06.2004), see Figure 9 and paragraph [0089].	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

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Date of the actual completion of the international search	Date of mailing of the international search report
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